Research Consent Form
Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates OHRS 01/06/12

Protocol Title: A Phase I Study of Vaccination with Autologous, Lethally Irradiated Colorectal Cancer cells Engineered by Adenoviral Mediated Gene Transfer to Secrete Human Granulocyte-Macrophage Stimulating Factor

DF/HCC Principal Research Doctor / Institution: Cristina R. Ferrone, M.D./ Massachusetts General Hospital

A. INTRODUCTION

You are being asked to take part in this clinical trial because you have been diagnosed with colorectal cancer which has spread to your liver. This research study is a way of gaining new knowledge about colorectal cancer that has spread to the liver. For purposes of this research, you will be referred to as a "participant." This research study is evaluating a vaccine using your irradiated colorectal cancer cells as a possible treatment for colorectal cancer that has spread to the liver. Although there are treatments available, which can control your disease for a limited period of time, there are currently no treatments that have been shown to cure colorectal cancer once it has spread to distant sites.

It is expected that about 15 people will take part in this research study.

This research consent form was created to help explain why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in the 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 back to your primary doctor.

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 at any time in the future.

If your colorectal cancer has spread to the liver, the best treatment for this is an operation. You will have a separate consent session and consent form to sign with your surgeon before you have the operation. You are urged to discuss any questions you have about this study with your physician.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

DFCI Protocol Number: 12-436	Approved Date (DFCI IRB Approval): 06/03/2019
Date Posted for Use: 06/10/2019	ClinicalTrials.gov Identifier: NCT01952730

You are being asked to participate in a Phase I clinical trial. Phase 1 clinical trials test the safety of an investigational combination of drugs. Phase I studies provide information on what effects, both good and bad, the Investigational agent might have on your disease. “Investigational” means that the intervention is still being studied and that research doctors are trying to find out more about it. It also means that the FDA (U.S. Food and Drug Administration) has not approved the treatment for your type of cancer.

The main purposes of this study are to determine:

- The amount of vaccine that can be made for your colorectal tumor cells
- If the vaccine can be given safely
- What the effects of the vaccine are, both good and bad
- How the vaccine affects your immune system
- Whether this vaccine might have any effect on the return of your cancer in the liver after surgical removal

This study is being done because there are currently no treatments which have demonstrated to cure disease which has progressed, or moved beyond the site of the primary site of disease (colon or rectum). These vaccinations will be given after you have completed the standard of care treatment as determined by your doctor.

Laboratory research has made vaccines from cancer cells by inserting genetic material from a protein called granulocyte-macrophage colony stimulating factor (GM-CSF) into the cancer cell. Once complete, the cancer cells are able to produce large amounts of GM-CSF. The vaccine made from these cells has a greater anti-tumor effect than cancer cells without GM-CSF. The purpose of this research study is to determine the safety of an investigational vaccine that will be made using your own colorectal cancer cells in the manner described above.

This vaccine has been used in several other research studies for treatment for other cancers (skin, lung, ovarian, sarcoma and leukemia.) Information from these other research studies suggests that this vaccine may help to reduce the risk of your colorectal cancer returning after you have your colorectal cancer surgery.

Due to these results in melanoma and several other tumors we are encouraged to use this vaccine approach in patients with liver metastases from colorectal cancer, after the cancer in the liver has been removed by surgery.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this study is voluntary. Instead of being in this study, you have these options:

- Standard treatment including chemotherapy
- Participation in another research study
- No therapy specific to your cancer
- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to treat the symptoms.

. Please talk to your regular doctor your options before you decide whether you will take part in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study. We will also provide you with a calendar that will be an easy reference for you to keep track of the procedures and when you get the vaccines in this research study.

Before the research starts (screening):

After you have given your consent to participate in this study, your study doctor will perform some tests to see if you are eligible to participate in the study. These tests may take place up to 21 days before the surgery to remove a liver tumor, which will be used to create the vaccines. Many of the following examinations are commonly done to determine diagnosis and/or stage of disease and you may have already had some or all of these evaluations. They may or may not have to be repeated.

- **Medical history**, including any information about any illnesses you currently have and a record of all the medications you are taking. **Physical examination**, which includes measuring:
    - Blood pressure
    - Temperature
    - Heart Rate
    - Height and weight

- **Performance status** to determine how well you are able to perform every day tasks.
- **Blood samples:** Tests will be performed to check certain levels in your blood as well as test for HIV (Human Immunodeficiency Virus), Hepatitis B virus, Hepatitis C virus, Human T-lymphotrophic virus, both type 1 and 2 (Anti-HTLV-I and II), Treponema Pallidum (syphilis) and Cytolomegalovirus (Anti-CMV).
- Routine blood Tests to check your overall health (approximately 4-5 tablespoonfuls).
- An assessment of your tumor by X-ray, CT (Computerized Tomography) scan, or MRI (Magnetic Resonance Imaging).
- **Blood pregnancy test** for women of childbearing potential

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

Research Study Plan:

If these tests indicate you are eligible for this study and you agree to participate, you will be referred to a surgeon for the surgical removal of tumor tissue from which the vaccine will be made.

The surgery will be performed at Massachusetts General. You will be asked to sign a separate consent form to give permission to the surgeon to perform this operation. That consent will describe the risks of the operation which involves removing the tumor cells from your liver.

After your surgery, there is a possibility that your physician will recommend other treatment before starting the vaccines if he or she feels it would be beneficial to your care and medically appropriate. This part of the treatment would not be experimental (for example, chemotherapy or radiation therapy)

Then, in this case, the vaccines made from your cancer will not be administered to you until at least 4 weeks after your last chemotherapy or radiation treatment. If the time between your operation and the first scheduled vaccine injection is 8 weeks or longer, we will ask you to undergo another chest, abdomen and pelvic CT scan and clinical blood work to confirm that it is still safe for you to proceed with the vaccines.

After this 4 week rest period, vaccine administration will occur as previously outlined.

If these tests indicate you are eligible for this study and you agree to participate, you will be referred to a surgeon for the surgical removal of tumor tissue from which the vaccine will be made.
The surgery will be performed at Massachusetts General Hospital. You will be asked to sign a separate consent form to give permission to the surgeon to perform this operation. That consent will describe the risks of the operation which involves removing the tumor cells from your liver.

It is important to know that sometimes we are unable to collect enough cells from the tumor collection. In those cases we can try to grow the tumor cells for a short period of time to get enough cells to make vaccine, but we can not guarantee that we will always be able to produce vaccine for every participant who undergoes tumor cell collection.

The vaccines created from your colorectal cancer cells are scheduled to be given to you on days 1, 8, 15 and then every two weeks after that until 6 total vaccines have been administered. The amount of vaccines is dependent on the total amount of cells collected when your colorectal cancer liver metastasis is processed and prepared into vaccine in our lab. It is hoped that you will receive at least six vaccines. All scheduled treatment will occur in the outpatient clinic.

The vaccines will be administered in two injections that will be placed underneath your skin. The two injections will be given at the same place on your body. The recommended sites are your arms, thighs or trunk area and the sites will rotate per vaccine.

Day 1: This is the first day of treatment on study. The following procedures are planned on this day:

- Update of medical history
- Physical Exam
- Blood Samples for Routine Labs (2 tsp)
- Required Blood Sample for Immune Studies (4 tsp). You will have blood taken for immune testing every ***month*** after starting the research study to monitor the cells in your immune system for 3 months and then every 3 months for the first 2 years. The blood will be frozen and stored for future analysis.
- Vaccine administration

- If enough cells can be grown, you will also receive an injection of cancer cells that have been killed but not able to secrete GM-CSF. This is done to measure the amount of reaction of your immune system caused by the vaccine alone.

Biopsies

Punch skin biopsies will be obtained 2 days after the first and fifth vaccinations This will consist of a small piece of skin tissue removed under local anesthesia. A small stitch will be placed after the biopsy. You will sign a separate consent form for this procedure.

Days 8 and 15: The following procedures are planned on this day:

- Update of medical history
- Weight and vital signs
- Blood samples for Routine Labs (2 tsp)
- Blood for Immune Studies for (4 tsp)
- Vaccine administration

Day 29 and every 2 weeks (until no more vaccines are available): The following procedures are planned at these visits:

- Update of medical history
- Physical Exam
- Weight and vital signs
- Blood samples for Routine labs (2 tsp)
- Blood for Immune Studies (4 tsp)
- Punch Biopsy
- Vaccine administration

	Visit 1 Screening	Visit 2 Day 1	Visit 3 Day 8	Visit 4 Day 15	Visit 5 Day 29	Visit 6 Day 43	Visit 7 Day 57
Medical History & Physical Exam	X	X	X	X	X	X	X
Blood Samples	X	X	X	X	X	X	X
MRI/CT scan	X						
Vaccine Admin		X	X	X	X	X	X
Pregnancy Test	X						
Weights/Vitals Signs	X		X	X	X		X
Skin Biopsy*		X (day 3)				X (day 45)	

* Punch skin biopsies will be obtained 2days after the first and fifth vaccinations.

After the final dose of the study drug

Your treating physician will determine if you are eligible to receive a second series of vaccinations. In addition, there must be sufficient numbers of cells for vaccine remaining from the original harvest or a new liver metastasis has occurred and been removed to make more vaccine.

If you give consent to participate in the repeat dose phase, you will be required to repeat the screening tests to see if you are still be eligible to participate in the study.

It is possible that additional rounds of vaccine therapy may be offered after the second round as long as it is appropriate in the opinion of your treating physician and additional tumor is available to make vaccine and you continue to meet the eligibility criteria.

Follow-Up:

Participants will be monitored every 3 months with a blood test (1 tsp) for the first 3 years and then every 6-12 months for a total of 5 years. Staging CT scans will be performed 3 months after the last vaccination, then every 6 months for the first three years and then yearly to year 5. After 5 years imaging will be at the discretion of the treating physician. Blood draws for immune research studies will occur every 3 months for 2 years after completing all vaccinations.

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

It is estimated that receiving all the vaccine created from your cancer cells would take about 3 months. A second course of vaccination, if administered, lasts approximately 3 more months.

The research doctor may decide to take you off the research study for many reasons including if:

- 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
- There are any problems with research funding or drug supply
- Your condition worsens
- Or other unforeseen reasons

If you are removed from the research study, the research doctor will explain to you why you were removed. If you are removed from the research study, you will still be followed for at least 15 years as mentioned in the section above.

In addition, you can stop participating in the research study at any time. However, before you decide to stop participating in this research study, we encourage you to talk to the research doctor and your regular doctor first.

New findings developed during the course of this research, which may relate to your willingness to continue participation will be provided to you by your doctor.

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

While on this study, you are at risks for the side effects described below. You should discuss these with your treating doctor. There may also be other side effects we cannot predict. Your doctor can prescribe other drugs to make some of these side effects less serious and make you more comfortable.

A significant risk to taking part in this study is the likelihood of receiving a treatment that is not effective in helping to treat your disease. This means that you many spend time and experience side effects of the vaccine treatment that does not provide you with any health related benefits.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Risks Associated with Vaccination

Risks Associated with GM-CSF:

Likely (More than a 50% chance that this will happen)

- Localized skin reaction
- Erythema (redness of the skin)
- Induration (firm swelling of the skin around the vaccine site)
- Pruritis (itching at the vaccine site)
- Fatigue
- Nasal congestion

Occasional (Between a 1-10% chance that this will happen)

- Pustular eruption
- Necrotizing vasculitis (inflammation of blood vessels)
- Recall erythema at previous injection sites
- General papular rash
- Fever
- Bone pain
- Malaise (A vague feeling of bodily discomfort)
- Diarrhea
- Liver damage (When your liver is not functioning properly this can cause fatigue, and jaundice (yellowing of the skin and eyes). Although this is usually mild and reversible, this can be serious or life threatening.)
- Kidney damage (When the kidneys do not work properly, wastes can build up in your blood, leading to swelling in the arms and legs, tiredness and weakness. This could become severe, requiring hospitalization and dialysis to clean the wastes out of your blood. If the wastes are not removed from your blood, this could cause seizures and be life threatening.)
- Thyroid gland abnormalities

- Leucopenia (Condition in which the number of white blood cells circulating in the blood is abnormally low. This increases the risk of infection, which may be serious or life threatening)
- Leukocytosis (Condition in which the number of white blood cells circulating in the blood is abnormally high)
- Anemia (Low number of red blood cells that can causes tiredness and shortness of breath. May require a blood transfusion.)
- Arthralgia (joint pain)
- Dyspnea (shortness of breath)
- Fluid retention (Build up of fluid in the body or extremities causing swelling)
- Serous effusions (Collection of fluid around the lungs in the chest cavity, which can cause shortness of breath and may require treatment)
- Return various auto-immune diseases (Conditions where the body's immune system attacks normal tissues.)

Rare (Chance of less than 1% this will happen)

Auto-immune diseases: There is a possibility of inducing an autoimmune reaction against normal body tissues. This is when your immune system may start to attack normal body tissues. No serious reactions such as these were observed in our other vaccine trials using GM-CSF as part of the vaccine.

Although your tumor cells will be killed to prevent their growth in you it is possible, though highly unlikely, that they may grow after being injected in you causing new tumor deposits.

Risks of Using Viruses in Making the Vaccine:

Since viruses are used to insert the GM-CSF into your tumor cells, it is possible that these viruses may still be present in the tumor cells and may be transmitted to you. Extensive testing will be performed prior to injection to try to make sure that no viruses are present. The consequences of transmission of these viruses to humans are unclear. This virus can produce an upper respiratory infection (common cold) or redness in the eyes (conjunctivitis) when it infects healthy people. Viral transmission has not been documented in any of the other clinical human studies using this type of virus.

Risks of Skin Biopsy:

This procedure may be associated with complications such as pain, bleeding, infection, scarring and problems with wound healing. Local anesthetic numbing agents may be associated in unusual cases with central nervous system effects, including lightheadedness, dizziness, blurred vision, ringing in the ears, seizures, or respiratory arrest, or cardiovascular effects including a slow heart rate or low blood pressure. Allergic reactions may also occur rarely.

Risks of Blood Draws:

Likely side effects of having your blood drawn are bleeding at the site, bruising and slight pain. Less likely effects are fainting and infection with inflammation of the vein at the site where the blood is drawn.

Reproductive Risks:
Because the vaccine used in this research study might affect an unborn baby, you should not become pregnant while on this research study. There may be risks which are currently unforeseen or unknown. Pregnant women must not take part in this research study; neither should women who plan to become pregnant during the research study.

Women who are able to have children will be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this research study. Any woman who finds that she has become pregnant while taking part in this research study should immediately tell her research study doctor and she will be removed from the research study. You should also not breast feed your baby while on this study.

Radiation Risks Associated with CT Scans:

While you are in this research study, CT scans may be used to evaluate your disease. The frequency of these exams is similar to that which you would receive as standard care. There is a very small risk of developing a new cancer as a result of the radiological evaluation and treatment for your cancer.

Risks Associated with MRI Scans:

When having an MRI (Magnetic Resonance Imaging) scan, you will lie still on a table that slides into a tunnel slightly wider than your body. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the

narrow cylinder. If you feel uncomfortable in confined spaces, please tell your doctor. Your doctor may give you a medication to make you feel more comfortable. MRIs use powerful magnets to make images. Therefore, persons with certain metal implants, such as pacemakers should not have an MRI. (If you have an implant or any metal in your body, please check with your study care doctor to know whether you can have an MRI or not.) For people without metal implants, there is no known health risks associated with exposure to the magnet. As images are taken, a loud banging noise will be produced. Earplugs or headphones will be available if needed. The MRI can be stopped at any time at your request, but the scan may not be complete.

There is a small risk with using the contrast agent that is injected into a vein during the scan. Recent information has suggested that gadolinium, the contrast agent, may contribute to kidney disease in people with poor kidney function. Therefore, we will monitor your kidney function closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study.

Rarely, some people have allergic reactions to the contrast agent. On rare occasions, allergic-type reactions (such as hives and itching) have occurred. Serious reactions (for example, drop in blood pressure or difficulty breathing or severe allergic reaction and death) are rare.

Non-Physical Risks:

There is a small chance that we are not able to produce vaccine from your tumor cells and this could cause some psychological distress because you would be unable to receive the vaccine. If this happens, your doctor will explain to you why the vaccines were not able to be produced.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

If you agree to participate in this study, there may or may not be direct medical benefit to you. We hope the information learned form this study will benefit other people with cancer in the future.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being 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. You can still get your medical care from your hospital or doctor.

If you choose to not participate, or if you are not eligible to participate, or if you 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.

It is important to tell the research doctor if you are thinking about stopping so risks from the vaccine can be evaluated by your research doctor. In some cases, the abrupt stopping of a drug can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

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

You will not be paid to participate in this study. We may use your samples and information to develop a new product or medical test to be sold. The sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

J. WHAT ARE THE COSTS?

Taking part in this research study might lead to added costs to you or your insurance company. You will not be charged for any laboratory costs associated with the insertion of the GM-CSF gene into your metastatic colorectal cancer cells from the liver. You will also not be charged for the vaccine administration.

Your insurance company will be charged, however, for other portions of your care while on study. Such charges might include routine blood tests, physical examinations, radiologic studies and surgical procedures associated with your care. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage. You or your insurance company will be charged in the event of a hospitalization. Please ask if you have any questions about added costs or if you expect any insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate you in the event of injury. You will receive no payment for taking part in this study.

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:

- Dana-Farber Cancer Institute: (617) 632-3455
- Massachusetts General Hospital: (617) 726-2191
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485

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:

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

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

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.

There are no plans for MGH to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

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.

L. WHAT ABOUT 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.

Medical information created by this study may become part of your hospital medical record. Information that does not become part of your medical record will

be stored in your study file. It may also become part of a DF/HCC research database called CORIS. Study files are coded and not labeled with your name. The code linking your name to the file will be kept in a safe location.

Information contained in your records is used by study staff and in some cases it will be shared with the sponsor of the study. If your information is being shared with the sponsor, no information that could identify you will be given to the sponsor. Occasionally, a sponsor representative may come to the study site to review your study files. This person will never take any information that can identify you back to the sponsor. There may be times when we are required by law to share your information. In those cases, we do not need your permission.

The results of this study may be published. You will not be identified in any publication without your permission.

M. 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:

Massachusetts General Hospital

- Cristina R. Ferrone, MD: (617) 643-6189

24-hour contact: MGH: Cristina R. Ferrone, MD at (617) 643-6189 or page at (617) 726-2000

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (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.

N. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law 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
    - 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;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); 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 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, and its agent(s):
- 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 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?

Federal law 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.

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

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

8. 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;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); 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.)

9. 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.

10. 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).
- 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 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.

11. 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.

12. 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?"

O. 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: 12-436	Approved Date (DFCI IRB Approval): 06/03/2019
Date Posted for Use: 06/10/2019	

Adult Participants

To be completed by person obtaining consent:

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, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ 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 illiterate

The consent form was read to the participant who was given the opportunity to ask questions.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

DFCI Protocol Number: 12-436	Approved Date (DFCI IRB Approval): 06/03/2019
Date Posted for Use: 06/10/2019	

☐ 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