Protocol Title: THE USE OF SEQUENCING TO GUIDE THE CARE OF CANCER PATIENTS

DF/HCC Principal Research Doctor / Institution: LEVI GARRAWAY, MD, PHD/ DFCI

A. INTRODUCTION

You are being invited to participate in a research study (the CanSeq study) to help doctors and scientists better understand why cancers occur and to develop ways to better treat and prevent them. The study is also to help researchers understand how best to communicate the results of complex genetic studies to patients and doctors, and to help them use that information to choose the best treatment path.

You are being asked to participate in the CanSeq study because you have cancer. Other than possibly providing an additional sample of blood (1 tube), possibly providing a saliva sample, and participating in study-related surveys and interviews, participating in the study involves no tests or procedures beyond those required for your care.

It is expected that about 400 people will take part in this CanSeq research study.

Some research studies are supported in some way by an outside source. The National Human Genome Research Institute (NHGRI), a part of the National Institutes of Health (NIH), is supporting this research study by providing funding for the research study.

This form explains why this research study is being done, what is involved in participating, the possible risks and benefits of the study, alternatives to participation, and your rights as a participant. The decision to participate is yours. We encourage you to ask questions about the study now or in the future.

Disclosure of external financial relationships: Two study investigators, Dr. Levi Garraway (principal investigator) and Dr. Nikhil Wagle (co-investigator) are consultants for and hold ownership in a company called Foundation Medicine, Inc. (FMI). FMI uses genetic technologies to learn more about patients' cancers. However, no product or service from FMI is being tested in this study, and no patient information or study results will be transferred to FMI. Furthermore, neither FMI nor any other commercial entity is providing funding to support this study.

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B. WHY IS THIS RESEARCH STUDY BEING DONE?

Cancers occur when the molecules that control normal cell growth (genes and proteins) are altered. Changes in the tumor genes and in the genes of normal cells are called “alterations.” Many of these alterations can be detected by directly examining cancer cells in a tumor or circulating in blood. Several alterations that occur repeatedly in certain types of cancers have already been identified. These discoveries have led to the development of new drugs that “target” those alterations. More remain to be discovered.

Some of the alterations are found in genes. Genes are composed of DNA “letters,” which contain the instructions that tell the cells in our bodies how to grow and work. Genes make proteins which actually carry out the instructions in our cells.

We would like to use your DNA to look for alterations in the genes in cancer cells and blood cells using a technology called “sequencing.” Gene sequencing is a way of reading the DNA to identify errors in genes that may contribute to the behavior of cells. Some changes in genes occur only in cancer cells. Others occur in normal cells as well, in the genes that may have been passed from parent to child. This research study will examine both kinds of genes.

The purpose of this research study is to perform gene sequencing (gene tests) on your cancer cells (obtained from biopsies or surgery) and normal tissues (usually blood). The results of the gene tests will be used to try to develop better ways to treat and prevent cancers. We will also study better ways to communicate the results of these complex gene tests to you and your doctors, and to help you and your doctors use this information to choose the best paths for treatment. As part of this work, we may also learn things about the genes in your normal cells; some of that information will also be shared with you and your doctors if you so choose.

Importantly, this study will use tissue specimens that have already been collected and stored in the pathology department as part of your clinical care or as part of other research studies you may be participating in. In this study, gene tests will be performed on material only after the necessary clinical tests have been performed. In general, no additional invasive procedures will be required.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this CanSeq research study is voluntary. Instead of being in this research study, you may continue to obtain your clinical care without participating in this study. Your decision not to participate will not affect your clinical care in any way.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

If you agree to take part in this study, we are asking your permission to obtain an additional sample of blood (1 tube), and possibly also a sample of saliva. Cells from blood and saliva contain normal, non-cancer cell DNA which is needed for the analysis.

One of the main reasons to study the genetic characteristics of cancers is to learn whether they can predict response to existing treatments. Therefore, in this study, we would also link the results of the gene tests on your cancer with medical information that has been generated during the course of your treatment. The medical information is contained in your medical record.

A small number of the gene test results may have importance for your health or treatment. For example, they might uncover gene alterations known to make cancers respond to (or be resistant to) specific therapies. Therefore, we are asking you to consider whether or not you would like us to inform your doctor and you about some of the results of these gene tests.

Your doctor may contact you about results of gene tests, but only if the results could impact your cancer treatment or other disease directly, or if you have given your permission for him or her to do so. In some cases, a research doctor may contact you to find out if you would be interested in participating in a different research study based on information that may have been found in your tissue or blood samples, or in your survey/interview responses. We will also ask you to provide the name and contact information for a relative who may know your whereabouts, or who could decide about using your information for research in the future, if you are not available to give permission yourself.

Some of your specimens, as well as some of the material generated during the analysis of your tissues or blood, may be useful for study in the future, with newer technologies and approaches. We are asking your permission to store these specimens and materials in a secure biological sample storage facility for possible later research.

We are also asking you to participate in two surveys related to the study at a few time points. These time points include when you first join the study, and after you receive any results from the gene tests done on your samples. The surveys seek to learn how you are thinking about this type of genetic analysis, and the ways in which the information can be shared with you that would be most helpful.

Some study participants will also be invited to take part in study-related interviews. The purpose of these interviews is to understand what you expect will happen as a result of the gene tests, and how the results of the gene tests may have affected you.

The surveys should take no more than 15 minutes to complete. The interviews are expected to take approximately 45 minutes to complete.

Finally, rapid progress in understanding and treating cancer will occur when some of the genetic information derived from your tissues and blood can be shared with other researchers. In particular, the National Institutes of Health (NIH) and other organizations have developed special data (information) repositories that analyze data and collect the results of certain types of genetic studies. These central banks will store your genetic information, samples, and survey/interview information and provide them to qualified researchers to do more studies. Therefore, we are also asking your permission to share your results with these special banks. Your information or samples will be sent only with a code number attached. Your name or other directly identifiable information will not be shared with data banks or other investigators. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research. Although there may be a slight risk of loss of privacy when sharing this information with these banks, we have established procedures to encode your samples and information and protect your data. Although we will do everything we can to protect the privacy of your data, we cannot absolutely guarantee its privacy or predict how genetic information will be used in the future.

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

You will be in this research study indefinitely unless you inform the Principal Research Doctor, Levi Garraway, MD, PhD, that you no longer wish to participate. You may do this at any time. Your decision to withdraw will not affect the care you receive. Information that may have been generated from your samples, surveys and/or interviews will not be destroyed if you withdraw;

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however, no further gene tests will be performed on your samples and the samples themselves will be destroyed.

F. WHAT KIND OF INFORMATION COULD BE FOUND IN THIS STUDY AND WILL I BE ABLE TO SEE IT?

The gene tests in this study are being done to add to our knowledge of how genes and other factors affect cancer. We are gathering this knowledge by studying groups of people. *For that reason we will not ordinarily give you the results of our research on your samples unless there is clear evidence of actions* that *could benefit your health or if you have given us permission to discuss the research findings with your doctor and you*. This is described in more detail below.

The gene tests being performed on your tissues and blood are designed to look for changes that might be associated with cancer. Some of these changes may be in genes in your cancer cells only; some will be in the genes in the normal cells as well. Changes in the tumor genes and in the genes of normal cells are called "alterations." While we are primarily looking at genes associated with cancer, some of these tests might discover unexpected gene alterations that are associated with diseases or medical conditions other than cancer.

The project has a committee of genetic experts who will review all of the gene test results from cancer cells and blood cells to help decide which, if any, may have implications for your or your relatives.

Information about some gene alterations will be given to your doctor and to you as a part of your routine cancer care. Information about gene alterations that are discovered through this research study that are not a part of routine cancer care, but that may impact your health or health-related decision making, will only be given to your doctor and to you if you give us permission to do so.

We will offer genetic counseling, if you wish, to help you to understand the potential implications of this kind of genetic information for you and potentially for your family members.

Information about gene alterations that are a part of routine cancer care, and that will be returned to your doctor and to you, includes:

- Information about alterations found in the genes of your cancer cells that may be used to help select cancer-related treatment(s). For example, if the tests show that your tumor has a genetic change that can be treated with a specific anti-cancer drug, we will tell your doctors about that result and your doctors may share that information with you.

Information about gene alterations that are not a part of routine cancer care, and that will *only be returned to your doctor and to you with your permission*, includes the categories listed below. Please read each of these items carefully. Later in this consent form, we will ask you to tell us whether or not you would like us to tell you and your doctor about each type of gene test result, if it is found in the tests on your cancer cells or normal cells. We will only share these types of results with you and your doctor if you give us permission to do so.

- Gene test results related to cancer:

    - Genes from your cancer cells may be found to contain an alteration that can be treated with a specific therapy available as part of a clinical trial (a type of research study).

    - Genes from your cancer cells may contain an alteration that is associated with better or worse prognosis (outlook) for your type of cancer.

    - Genes from your normal blood cells may contain an alteration that is associated with an increased risk of developing cancer such as colon, lung or breast cancer. If you are found to have such an alteration, some of your family members may also share it. If so, they may also have an increased risk of developing certain cancers.

    - Genes from your normal blood cells may contain an alteration that affects the way your body handles a cancer medication. This information might mean that you need a higher or lower dose than usual for that cancer medication.

- Gene test results not related to cancer:

  - Genes from your normal blood cells might contain an alteration that is associated with having a condition other than cancer, or an increased risk of developing a condition other than cancer, that **can** be treated. The risk would also be there for any of your blood relatives who share that genetic alteration. For example, tests might show that you have a higher than average risk of developing heart disease. In this example, there might be proven interventions or treatments to help you avoid heart disease (such as changes to your diet or giving you medication).

  - Genes from your normal blood cells might contain an alteration that is associated with having a condition, or an increased risk of developing a condition, (other than cancer) that **cannot** be treated. For example, tests might show that you have a higher than average risk of Alzheimer's disease. In this example, there are no proven interventions or treatments to help you avoid Alzheimer's disease.

  - Genes from your normal blood cells might contain an alteration that affects the way your body handles a non-cancer related medication. For example, tests might show that your body handles a blood-thinning drug faster or slower than average. This information might mean that you need a higher or lower dose than usual for treatment.

  - Genes from your normal blood cells might tell us about whether you carry an alteration for a condition (other than cancer) that you might pass on to your child. This is possible even if you do not have the condition yourself. For example, tests might show that you carry a gene alteration for cystic fibrosis that could be passed on to your child.

If the study reveals information about a gene alteration that can significantly compromise your health in the near future, and if we have proven ways to treat or reduce the health risk associated with that alteration, we may tell your doctors and you about the test result in order to give you the best medical care possible. If this situation arises, the study investigators may tell you and your doctor information about this alteration even if you have not previously given us your permission to do so.

Other gene alterations may be found that do not have clear implications for your health or the health of relatives. Alterations that are not considered significant (have a proven medical impact) will not be shared with you or your doctor at this time.

Because new knowledge may result in reclassifying some alterations as important in the future, at the end of this form we will ask you to provide the name and contact information for a relative with whom you would like us to share information about your gene tests in case you are not able to receive it yourself.

It is important to recognize that the gene sequencing tests performed in this study may not identify any information that is important to your health or cancer treatment. Thus there is no guarantee that any information generated in this study will be returned to you and your doctor.

There is also a chance that the gene sequencing tests may not be able to be performed or completed, due to issues with inadequate tumor specimen or technical issues that arise during the testing. In the event that the gene sequencing tests are not able to be completed, you will be notified but no genetic information will be returned to you and your doctor.

The surveys include questions about whether you are experiencing any symptoms of anxiety and depression. If your answers show that you are at high risk for anxiety or depression, we will tell your doctor about this so that she or he can take appropriate measures to treat or prevent these conditions, if needed.

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

The major risk of participating in this study is that the gene test results, including the identification of genetic abnormalities in you or your cancer, could be seen by unauthorized individuals. We have tried to minimize this risk by carefully limiting access to the computers that would house your information to the staff of this research study.

There are small risks associated with obtaining the additional tube of blood. You may experience slight pain and swelling at the site of the blood draw. These complications are rare and should resolve within a few days. If they do not, you should contact your doctor.

If you had (or will have) surgery to biopsy or remove part of your cancer, the pathology department at the hospital where you had the surgery or biopsy will be asked to share some of the tissue that was (or will be) removed during the procedure. We will use a small part of this tissue, and will return the remainder to the hospital from which it was obtained. It is a common practice for part of the stored tissue to be used for research. The hospital will keep a portion of your original tissue for future clinical purposes. If there is not enough tissue in the original sample for clinical uses and for research, too, then the hospital will not release it to the study for research purposes.

There is a small but real risk that if your samples are used for this research study, they might not be available for clinical care in the future. However, we have attempted to minimize this risk in two ways. First, the pathologists in the department of pathology where your specimens are kept will not release your specimen unless they believe that the material remaining after the research test is performed is sufficient for any future clinical needs. Second, if your specimen is stored in a tissue bank or biorepository, then a designated group of clinicians and scientists who oversee the bank will release your specimen only if they think that the research being performed justifies the use of your material. This step is designed to help ensure that your specimens are being used for the best possible scientific purposes and to help minimize the possibility that your material will be used up.

There are also risks or discomforts associated with learning the results of genetic testing. These might include the following:

1. Learning that your DNA contains a gene alteration that is associated with an increased risk of a disease could cause depression, anxiety, anger, or fear of future events.

   Another risk of this study is that you may feel upset when answering study-related questions. If you start to feel upset during the survey or interview process, you may stop the survey or interview at any time. You may also choose not to answer any question for any reason. If you do feel upset and would like to talk to a psychosocial provider (psychologist or social worker), just let us know.

2. This information could affect your relationship with family members. Some insurance companies might consider an inherited, disease-associated gene alteration to be a new “pre-existing condition” and you might be obligated to disclose this information prior to obtaining new

health or life insurance. We think that the chance of this happening is small. A national law, the Genetic Information Non-Discrimination Act (GINA), provides protection against genetic discrimination by health insurers and employers under certain circumstances. If you already have or have had cancer, any new gene testing is unlikely to change an insurer's view of your risk.

3. The laboratory studies may find no cancer-related abnormalities in your specimens. In that case, you might have gone through this testing process and not learned anything about your cancer or your risk of cancer. Current technologies are not able to find and identify every possible gene alteration that might be related to cancer. You may still have genetic or other alterations that are related to your cancer or your cancer risk but the tests we perform may not be able to detect them

4. Family members may be upset to learn that they may be at risk for cancer or other diseases and that they learned this through your participation in this study.

5. We may not inform you about gene test results regarding diseases for which there are no effective and available monitoring or treatment strategies. Therefore, you may be falsely reassured about your health or risk status if we do not report specific findings to you.

   All testing methods have an error rate and it is possible that a result we report to you or your doctor may have been an error. We attempt to reduce this possibility by monitoring our testing and trying to reduce the error rate. In addition, we will only report results that have been generated or reproduced in a laboratory that is certified by the government for its consistency and accuracy (called a CLIA laboratory).

H. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

It is important to understand that this is not a clinical study being done to benefit you directly. Therefore, taking part in this research study may not directly benefit you. However, the results of the gene tests on your blood and tumor may lead to information that will be helpful in choosing the best treatment for you. It may also lead to information that can help you take other steps to benefit your health. Some of this information may also be helpful to family members. Finally, by joining this study, you will help us understand how to use gene tests to improve the care of patients with cancer in the future.

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

You have the right not to sign this form. If you decide not to sign it, you cannot participate in this research study. If you do sign the form, you can stop being in the research study at any time. Please notify Dr. Levi Garraway, the study Principal Research Doctor, in writing if you decide to stop. You may also withdraw from the study by filling out a "Withdrawal of Consent to Continue in Research Form." Your doctor, or a member of our study team, can provide you with a copy of this form.

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

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

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

K. WHAT ARE THE COSTS?

Taking part in this research study might lead to costs to you or your insurance company. However, these should not exceed the costs that would otherwise be associated with your care. For example, some of the gene tests performed on your tissues or samples may be similar to those that your doctor would obtain as part of your clinical care. In that case, we would bill your insurance company for performing those tests and you may be responsible for co-payments and deductibles that are typical for your insurance coverage. You and your insurance company would only be billed once for these tests.

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
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485

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L. 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 Dana-Farber Cancer Institute 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.

M. 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 research 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 clinical database called CORIS, a research database called CRDR, or other research databases.

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

N. 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

- Nelly Oliver, PhD (617) 582-8706
- Levi Garraway, MD, PhD (617) 632-6689
- Pasi Janne, MD, PhD (617) 632-6076
- Stacy Gray, MD, AM (617)- 582-9651

- Judy Garber, MD, MPH (617) 617-632-5770

24-hour contact: DFCI: Nikhil Wagle, MD (617) 632-4940 or page at (617) 632-3000, beeper 41756.

For questions about your rights as a patient, 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. Please keep a copy of this document in case you want to read it again.

O. 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 this 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 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**

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 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. To request this information, please contact your doctor who will request this information from the study directors.

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P. Participation Options

You may choose to receive some gene test results that may be discovered through this study. Please read each sentence below and think about your choice. After reading each sentence mark "Yes" or "No" and initial next to your choice.

We will honor your choices as best we can. However, if the study reveals information about a gene alteration that can significantly compromise your health in the near future, and if we have proven ways to treat or reduce the health risk associated with that alteration, we may tell your doctors and you about the test result in order to give you the best medical care possible. If this situation arises, the study investigators may tell you and your doctor information about this alteration even if you have not previously given us your permission to do so.

No matter what you decide to do, it will in no way affect your care. If you have any questions, please speak with your doctor or nurse. You may change your responses to any of the questions below at any time during your participation in the study. If you would like to change your responses to these questions, please contact Nelly Oliver, the Project Manager, at 617-582-8706, or by email at DFCI_CanSeqU01@DFCI.HARVARD.EDU.

You have my permission to tell my doctors and me about any gene test result *related to cancer* that…

o Might qualify me for a clinical study of a research drug.

_____ YES _____ NO (Please initial one)

o Might tell me that I have a **better** than average prognosis (outlook) for my type of cancer

_____ YES _____ NO (Please initial one)

o Might tell me that I have a **worse** than average prognosis (outlook) for my type of cancer

_____ YES _____ NO (Please initial one)

o Might identify me (and possibly my family members) as having an increased risk of developing certain cancers.

_____ YES _____ NO (Please initial one)

o Might tell me about how my body handles chemotherapy or other cancer medications.

_____ YES _____ NO (Please initial one)

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You have my permission to tell my doctors and me about any gene test result *unrelated to cancer* that…

o Might identify me (and possibly my family members) as having a condition, or having an increased risk of developing a condition, *other than cancer* that **can** be treated.

_____ YES _____ NO (Please initial one)

o Might identify me (and possibly my family members) as having a condition, or having an increased risk of developing a condition, *other than cancer* that **cannot** be treated.

_____ YES _____ NO (Please initial one)

o Might tell me about how my body handles non-cancer-related medications.

_____ YES _____ NO (Please initial one)

o Might identify me as carrying a gene alteration for a non-cancer-related condition that I might pass on to a child (even if I do not have the condition myself).

_____ YES _____ NO (Please initial one)

If you use email, we would like to offer you the option to complete surveys for this study via the internet. Please check a box below to indicate whether we may use email to send you links to study-related surveys.

___ Yes, you may use email to communicate with me about study-related surveys. My email address is:

_____

___ No, please do not use email to communicate with me about study-related surveys

___ I do not use email

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If my health condition changes and I am unable to receive medically significant results of this research, I allow my doctor to discuss these results with an alternative individual, whom I will *designate below.*

Please provide the name and contact information of your designate:

_____(name)

_____(relationship)

_____(phone number)

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Q. DOCUMENTATION OF CONSENT

My signature below indicates:

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

Signature of Participant Date

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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: _____

☐ 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

DFCI Protocol Number: 12-078	Date DFCI IRB Approved this Consent Form: 08/25/2014
Date Posted for Use: 10/09/2014	Date DFCI IRB Approval Expires: 08/24/2015
OHRS Version Date: 06/25/2013	