Protocol Title: A Phase I/II Trial to Evaluate the Safety and Tolerability of Alectinib and Bevacizumab in Patients with Advanced, ALK-Positive, Non-small Cell Lung Cancer

DF/HCC Principal Research Doctor / Institution:
Justin Gainor, MD / Massachusetts General Hospital

Phase II Consent

A. INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have advanced non-small cell lung cancer (NSCLC). For purposes of this research, you will be referred to as a "participant." This research study is evaluating two drugs, alectinib and bevacizumab, as possible treatments for NSCLC.

It is expected that approximately 20 patients will take part in the Phase II portion of the study

Genentech/F. Hoffmann- La Roche, Ltd., a pharmaceutical company, is supporting this research study by providing funding for the research study as well as the study drugs.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, 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 this 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 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.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

This is a Phase I/II clinical trial. You are being asked to participate in the Phase II portion of the study. A Phase II clinical trial tests the safety and effectiveness of an investigational intervention to learn whether the intervention works in treating a specific disease. “Investigational” means that the intervention is being studied.

In this research study, we are investigating the combination of two study drugs: alectinib and bevacizumab. The FDA (the U.S. Food and Drug Administration) has not approved alectinib as a treatment for any disease.

It has been found that some people with NSCLC have a change (mutation) in a certain gene called the anaplastic lymphoma receptor tyrosine kinase (ALK) gene. This mutated gene helps cancer cells grow. Alectinib belongs to a class of drugs designed to inhibit ALK. This drug has been used in other research studies. Information from those other research studies suggests that alectinib may be effective in killing cancer cells that have changes in ALK. Only participants with changes in the ALK gene will be allowed to participate in this study.

In this research study, alectinib will be combined with bevacizumab. Bevacizumab (also called Avastin) works by slowing or stopping the growth of cells in cancer tumors by decreasing the blood supply of the tumors. If blood supply is decreased, oxygen and nutrients that are needed for tumor growth are decreased. The FDA has approved bevacizumab as a treatment option for your disease

The purpose of this study is to test the safety of alectinib and bevacizumab. We will also determine how effective this combination is in participants with advanced, ALK-positive NSCLC.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Receive standard treatment including crizotinib (XALKORI) or ceritinib (Zykadia).
- Receive standard chemotherapy

- Receive radiation therapy to brain metastases.
- Take part in another research study.
- Receive 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 the research doctor about your options before you decide whether you will take part in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Since we are looking for the highest dose of the study drug that can be administered safely without severe or unmanageable side effects in participants that have ALK-positive lung cancer, not everyone who participates in this research study will receive the same dose of the study drug. The dose you get will depend on the number of participants who have been enrolled in the study before you and how well they have tolerated their doses.

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.

If you take part in this research study you will be given a drug diary. You will be asked to document information in the drug diary about the study treatment you are being asked to take.

Before the research starts (screening):
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies.

- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Physical exam,** including measurement of height, weight and vital signs (temperature, breathing rate, blood pressure and pulse).
- **An assessment of your tumor** by one or more of the following standard assessment tools: CT (Computerized Tomography) scan and MRI (Magnetic Resonance Imaging)
- **Blood tests,** for standard laboratory tests (about 2 tablespoons), a pregnancy test (if you can become pregnant), and tests to check how quickly your blood clots.
- **Urine test**.
- **EKG,** a test that measures the electrical activity and rhythm of the heart.
- **Patient questionnaires,** which include questions about your health

If these tests show that you are eligible to participate in the research study, you will begin the study treatment. 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:
Each treatment cycle last 21 days (3 weeks).

Alectinib is a capsule that you take by mouth. You will be given a drug diary to record the dose of alectinib you take each day. The diary will also include special instructions for taking alectinib.

You will be given Bevacizumab via IV, which is called an infusion.

You will receive an infusion of bevacizumab on the first day of each treatment cycle (once every 21 days).

During the COVID19 pandemic, your doctor may hold or discontinue Bevacizumab infusions. If Bevacizumab is held or discontinued, your visits and assessments may be every 42 days (6 weeks).

Study Treatment Period
A schedule of clinic visits for the study is summarized below. At every visit, you should tell the study staff how you are feeling and whether your health has

changed. You may have other lab tests done as part of your cancer care in addition to those listed below.

Cycle 1 Day 1:

- **Performance status**.
- **Physical exam**.
- **Routine blood tests** (about 2 tablespoons of blood).
- **Urine test.**
- **EKG**.
- **Patient questionnaires**.

Cycle 1 Day 15:

- **Performance status**.
- **Physical exam**.
- **Routine blood tests** (about 2 tablespoons of blood).

Cycles 2-10
Day 1 of Each Cycle

- **Performance status**.
- **Physical exam**.
- **Routine blood tests** (about 2 tablespoons of blood).
- **Urine test.**
- **EKG** only be performed on Day 1 of Cycle 2 and Cycle 8.
- **Patient questionnaires**.
- **An assessment of your tumor**. You will only have brain MRIs performed if abnormalities were detected on the initial screening MRI.

Cycles 11 and Beyond
Day 1 of Each Cycle

- **Performance status**.
- **Physical exam**.
- **Routine blood tests** (about 2 tablespoons of blood).
- **Urine test.**
- **EKG** only be performed on Day 1 of Cycle 18.
- **Patient questionnaires**.
- **An assessment of your tumor**.

End of Study Treatment Visit

When you stop alectinib and bevacizumab permanently, you will return to the study clinic. The following procedures will be done at this visit:

- **Performance status**.
- **Physical exam**.
- **Routine blood tests** (about 2 tablespoons of blood).
- **Urine test.**
- **EKG**.
- **Patient questionnaires**.
- **An assessment of your tumor**.

30 Day Follow-up Visit
You will also visit the clinic 30 days after you stop taking study drugs. The following tests and procedures will be done:

- Review of medical history and medications
- Patient questionnaires

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

You will be in this research study for up to a year.

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
- Your condition worsens
- A decision is made to close the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed.

In addition, you can stop participating in the research study at any time. However, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

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

There are risks to taking part in any research study. One risk is that you may get a study drug or study dose of a drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

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 Alectinib:

Common (occurs in greater than 10% of patients)

- Loss of taste

- Abnormally high levels of bilirubin in the blood. (Bilirubin is a bile pigment produced by the liver which is normally and continually excreted from the body). This may indicate that too many red blood cells are being destroyed, or that the liver or gallbladder is not functioning properly.
- Constipation
- Increase in liver enzyme, indicating possible liver damage (AST/ALT increase)
- Nose and throat inflammation (nasopharyngitis)
- Rash
- Abnormal kidney test which may indicate possible kidney damage (blood creatinine increase)
- Low white blood cell count which may increase your risk for infection, such as pneumonia and/or severe blood infection (neutrophil count decrease)
- Increased blood level of enzyme from muscle which may indicate possible muscle damage (Blood CPK increase)
- Muscle pain (myalgia)
- White blood cell decrease (which may increase your risk of infection)
- Blood alkaline phosphatase increase (which may indicate possible liver damage)
- Oral inflammation (stomatitis)
- Nausea
- Weight increase
- Diarrhea
- Feeling of bodily discomfort (malaise)
- Bradycardia (slow heart rate)

Alectinib also contains a substance called sodium lauryl sulfate that is known to sometimes cause gastrointestinal problems, such as nausea, vomiting and diarrhea.

Rare but serious:

- Interstitial lung disease (ILD; lung scarring) which could cause breathing difficulty, cough, and fever. ILD can be life threatening.
- Low blood pressure and slower blood clotting.

Eye disorders, such as blurred vision.

Risks Associated with Bevacizumab:

Frequent (Chance of 10-50% that this will happen):

- Nausea and vomiting
- Headaches
- High blood pressure, with increased risk of heart problems, headache, and stroke.
- Pain
- Abdominal pain
- Shortness of breath
- Mouth sores
- Weakness
- Upper respiratory infection
- Chills
- Loss of appetite
- Bleeding (including in stomach or intestines)
- Runny nose or increase in tears in your eyes
- Kidney damage, found by testing your urine
- Loss of function of the ovaries, which can lead to menopause

Occasional (Chance of 5-10% that this will happen):

- Hoarseness
- Nosebleeds
- Low levels of potassium in the blood which can cause an irregular heart beat
- Hair loss
- Dry skin
- Hole in your intestine may occur which may require hospitalization and/or surgery which could be serious or life threatening.
- Blood clots in your veins and arteries. These can cause chest pain, heart attack, or stroke. A blood clot in your eye might cause vision loss. Clots can be serious and life threatening.
- Allergic reaction when the infusion is given. A serious allergic reaction may result in death.
- Slowed growth and development (based on laboratory studies)

Rare (Less than 5% chance this will happen):

- Inability of heart to pump blood properly, which can cause weakness and tiredness, fluid retention, and fluid build-up in the lungs, which can cause shortness of breath (congestive heart failure)

- Decreased ability of your wounds to heal. This can lead to infections, hospitalization, or could possibly be fatal.
- A very rare problem in your brain that may cause confusion, blindness, and coma. This is associated with very high blood pressure and is not thought to be a permanent condition.
- Confusion
- Abdominal abscess or infection in your abdomen
- Fistula or hole in your bowel. This is an abnormal connection between two different organs and may lead to life threatening complications including serious infections, bleeding, or dysfunction of the organs
- Dehydration
- Abnormal bleeding from in your body or from the tumorwhich could be serious of life threatening

Cancer research often includes biopsies, scans, x-rays that are also provided as routine care. The following describes the side effects of procedures done only for the purposes of research.

Radiation Risks Associated with Scans and X-Rays:
While you are in this research study, CT scans may be used to evaluate your disease. The frequency of these exams is slightly greater than what you would receive as standard care. In the long term, over many years, there is a very low 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 research doctor. Your doctor may give you a medication to make you feel more comfortable. 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.

Risks Associated with Contrast Agents Used During Scans:
There is a small risk with using a contrast agent that is injected into a vein during CT scans and MRIs. The contrast agent is a special dye that highlights organs, blood vessels or tissue to make them more visible. Depending on the type of

contrast agent that is used, it may cause decreased kidney function or worsen kidney function in people who already have decreased 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.

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

Reproductive Risks:
The drugs used in this research study may affect a fetus. While participating in this research study, you should not become pregnant or father a baby, and should not nurse a baby. We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

If a female becomes pregnant while on this study or within 90 days after the last dose of the study drug, a report should be completed and provided to the sponsor. We would also like to follow-up with you to obtain the outcome of the pregnancy if this occurs.

Non-Physical Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

The questionnaires used in this study may be upsetting. If you find the questionnaires upsetting, you may speak with the research doctor or ask to be referred for additional emotional support.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

This study may or may not help you. Taking part in this research study may help us learn more about alectinib and bevacizumab as treatments for ALK-positive lung cancer that may help people 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 outside of the 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.
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 study drugs. 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 for participation in this study.

We may use your samples and information to develop a new product or medical test to be sold. The hospital, Genentech/F. Hoffmann- La Roche, Ltd., 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 alectinib and bevacizumab.

You or your insurance company will be charged for portions of your care during this research study that are considered standard care. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

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:

- Massachusetts General Hospital: (617) 726-2191

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)

K. WHAT HAPPENS IF I AM INJURED OR 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.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. The treating hospital 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/Partners CancerCare (DF/PCC) on behalf of the Dana-Farber/Harvard Cancer Center (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.

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 research study may become part of your hospital medical record and may be forwarded to your primary doctor. 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.

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

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. 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 (MGH)
Justin Gainor, MD: 617-724-4000

24 hour Contact: Call Dr. Gainor at 617-724-4000 and ask the doctor to be paged.

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, 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;
- 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 for the purpose of this or other research relating the study drug and its use in cancer; 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 supporters of the study, its subcontractors, and its agent(s): Genentech/F. Hoffmann- La Roche, Ltd.
- 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?"

O. OPTIONAL RESEARCH STUDIES:

One goal of this study is to learn more about who may best respond to the study drugs alectinib and bevacizumab. During this study, if feasible and if you consent, fresh tumor biopsies will be performed during screening and/or after you stop receiving the study drugs. These samples, along with stored tissue samples, will be used to learn how cancer cells respond to alectinib and bevacizumab. The samples will also be used to sequence the ALK gene and other genes thought to be important in cancer. This information may help us understand which patients will respond best to alectinib and bevacizumab, and why other ALK inhibitors stop working. The research tests performed on your tissue will not benefit you directly, but could help other patients in the future.

If you agree, fresh tumor biopsies will be done at the screening visit and/or at the time of disease progression, if your study doctor thinks the biopsies will be feasible and safe. Tests done on the tissue collected at these biopsies will be done to help us learn more about who may or may not respond to the study drugs alectinib and bevacizumab. You will have a chance to agree or not agree to have fresh biopsies collected below.

Risks associated with biopsies:
Biopsies are normally performed under the guidance of an imaging technique. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.

- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

Additional risks of a lung biopsy may include:

- Collapse of your lung during or following the biopsy.
- Severe bleeding.
- Infection such as pneumonia. Usually this type of infection can be treated with antibiotics.
- Spasms of the breathing (bronchial) tubes, which can cause breathing difficulties right after the biopsy.
- Irregular heart beat (rhythm).

Uncommonly, complications from biopsies can be life-threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

Permission for biopsy to collect fresh tumor tissue during this study
Please indicate whether or not your wish to undergo a biopsy or biopsies to provide additional tumor tissue for research tests by choosing one of the options below and writing your initials in the space provided.

☐ Yes _____Initials _____Date

☐ No _____ Initials _____Date

DFCI Protocol Number: 15-055	Approved Date (DFCI IRB Approval): 12/28/2020
Date Posted for Use: 01/06/2021	

P. 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: 15-055	Approved Date (DFCI IRB Approval): 12/28/2020
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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

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