Participant Informed Consent for Clinical Research

Study title for participants: **Taxi HAILL: A Three-Arm Cluster Randomized Controlled Trial Examining Health Care Access Interventions for Taxi Drivers**

Official study title for internet search on http://www.ClinicalTrials.gov:
Randomized Controlled Trial Examining Health Care Access Interventions for Taxi Drivers

Subtitle: Drivers Consent Form

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If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to your child, if the participant is a minor, or to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

What am I being asked to do?

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

We are asking you to take part in this research study because you are a Taxi driver in NYC who attended a health fair at one of the garages/sites that has agreed to participate in the study, and based on the answers to questions you answered as part of your health fair form, you are eligible to participate.

Taking part in this study is your choice.

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

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered. See the *Where can I get more information?* section of this document for more information about research studies and for general information about cancer.

Why is this study being done?

This study is being done to answer the following question:

What is the most effective way of following up with drivers who attend our health fairs, to make sure taxi drivers go to important medical appointments and have a regular doctor to help with their health problems?

What is the usual approach?

In order to help drivers learn about their health, the Immigrant Health and Cancer Disparities (IHCD) Service at Memorial Sloan Kettering Cancer Center has held health fairs across New York City taxi garages and sites frequented by drivers (e.g. airport holding lots, place of worship, etc.) to give drivers free weight, height, waist size, blood pressure, cholesterol, and blood sugar level screenings, and to provide results of these tests. We have also given information on how to get health care in New York City. The usual approach for participants who are not in a study is to participate only in the health fair.

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

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

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

We are now doing a study to build on our health fairs service program. At the health fair, you will complete an intake survey that will ask questions about your background (e.g. age, gender, country of birth, driving history, workplace and earnings), health care access, smoking habits, exercise and eating habits, stress, and medical history including cancer screening history. Please note that if you did not fully complete this form during the health fair, we will schedule a time to meet with you (in person or over the phone) to complete it within the next two weeks. We will also take your health measurements on height, weight, waist circumference, and blood pressure. As a participant of this study, we will receive a copy of everything you have completed at the health fair.

You will discuss your results with a doctor or a nurse and we may give you advice about low cost health care options in your neighborhood. Finally, we will obtain a copy of the advice given to you by the doctor or nurse at the end of the health fair.

After finishing the intake form, you will be randomly assigned to 1 of 3 study groups.

- Group 1 (Health Fair Only) – we will test our usual health fair service by having our health fair staff follow up with drivers who are told that they need to see a doctor due to a high blood pressure reading, or if they have any other unusual result that needs a physician follow-up
- Group 2 (Health Fair + Navigation Case Management) – all participating drivers will be connected to a trained Navigator Case Manager, who will check in with the driver at least once a month about going to any necessary medical appointments, and the case manager will help the driver find a routine doctor.
- Group 3 (Health Fair + Taxi health Improvement Promoter (TIPs) + mobile text messaging (mTECH)) – we will follow up after the free health screenings by using mobile text messaging sent by our staff to remind drivers to make and attend any necessary medical appointments; staff will also send weekly text messages on healthy living advice for drivers. Additionally, drivers in Group 3 will be connected to a Taxi health Improvement Promoter, or TIP. TIPs are trained taxi drivers who will check in with drivers weekly/monthly to remind them about necessary medical appointments.

Before the start of this study, we spoke with several taxi garages/sites frequented by drivers that agreed to take part in this study. Each garage/site was randomly put into one of three different study groups.

This was assigned by a computer so that each garage/site had an equal chance (like a flip of coin) of being assigned to any group.

Today you will be assigned to one of the three groups based on which group was randomly assigned to your garage or enrollment site.

For this study, we will follow-up with you at 3 months, 6 months and 12 months after the health fair date.

At the 3 and 6 months mark, we will call you to set up a time to complete a brief follow-up survey that will take about 15-20 minutes to complete in person or on the phone. This survey will ask you questions about your health and use of healthcare.

At the 12-month mark, we will contact you again, to set up a time to complete a 1 year follow-up in person for about 15-20 minutes. We will meet with you in person at our office, or at your garage base/enrollment site, for follow-up. At this meeting, we will ask you the same survey questions on your health and use of healthcare and a trained staff member will take the same health measurements (height, weight, waist size, blood pressure) that you did at the first health fair. This study is approximately 12 months. In case we are unable to reach you, we will continue our efforts to reach you up until 6 months past your 12-month mark.

If you attend a medical appointment with a general doctor, we will also ask you to hand in any documentation of your appointments, which may include exit instructions, a doctor's note, explanation of benefits or payment receipt.

All surveys will be completed with you in your preferred language or a language that you speak well (English, Bengali, Urdu, Spanish, or French).

All information collected from you, including personal information, survey answers, and health measurements, will be linked to your study ID number only. Your name will not be linked to study data collected.

After you are finished with the study, the research team may contact you if any survey answer is unclear. If you agree, we may contact you in the future about other studies you might be interested in.

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

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

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

If you choose to take part in this study:

- You may be asked sensitive or private questions.
- You may find out that you have health problems or unmet clinical needs, which may make you feel stressed. You will be asked to tell us about any feelings of stress, or specific medical concerns to

research staff. Research staff will be trained to tell study doctors who will refer you to low cost community health services when necessary.
- The study doctor or nurse will counsel you and our trained staff will offer to escort you to a nearby emergency room (or urgent care facility of your choice) for follow-up care if the results of your health fair screening or follow-up measurements indicate an urgent medical need. You have the right to refuse this service, but we will urge you to arrange a follow-up medical appointment to get necessary care.

There may be some risks that the study doctors do not yet know about.

Benefits
You may benefit from taking part in the study by getting information and services at a convenient location that you may not have known about before. You may also benefit from knowing that this research may help others. This study may help us find better ways of helping taxi drivers get healthcare and live healthier lives. We believe that what we learn in this study will lead to better care for taxi drivers in NYC.

If I decide to take part in this study, can I stop later?
Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?
Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), study funder, National Institute of Nursing Research (division of NIH) or study sponsor, Memorial Sloan Kettering Cancer Center. The study sponsor is the organization that oversees the study

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?
The purpose of this study is to compare the effectiveness of providing the usual health fair service and follow-up alone plus additional interventions of Navigation Case Management (NCM) or mobile text

messaging (mTECH) and Taxi health Improvement Promoter (TIP). The addition of NCM or mTECH and TIP to the usual follow-up could prove to be more effective in finding the best way to make sure taxi drivers go to important medical appointments and have a regular doctor to help with their health problems. This study will help researchers find out whether the different approaches are better, the same as, or worse than the usual approach. To decide if any of the new approaches is better, the researchers will be looking to see if the study approach increases the likelihood of the drivers to go to important medical appointments and have a regular doctor to help with their health problems by 6 months or more, compared with the usual approach.

In our previous work, we found that many taxi drivers do not have a regular doctor, called a primary care doctor, that they can go to for health concerns. We are now doing a study to build on our health fairs service program, as described previously. We want to find out what is the best way to assist drivers with going to important medical appointments and finding a regular doctor to help with health problems.

About 900 people will take part in this study.

What are the study groups?

This study has 3 study groups:

- Group 1 (Health Fair Only)
  We will test our usual health fair service; after drivers get free weight, height, waist, and blood pressure testing, our health fair staff will follow up with drivers who are told that they need to see a doctor due to a high blood pressure reading, or if they have any other unusual result that needs a physician follow-up.
- Group 2 (Health Fair + Navigation Case Management)
  In addition to the health fair services with general follow-up, you will be assigned a Navigator Case Manager who will work with you after the health fair to assist with setting up any needed medical appointments or additional health care needs. A Navigator Case Manage is one of our specially trained team members who has learned all about signing up for health insurance, how to use one's insurance card, and resources in NYC on where to get care. Our navigator case managers have experience with helping New Yorkers get insurance and finding a regular doctor. You will be connected to a navigator case manager who will work with you monthly to make sure that you get the information and support you need to make any necessary medical appointments and find a regular doctor that can work with you any health problems.
- Group 3 (Health Fair + TIP + mTECH)
  In addition to the health fair services with general follow-up, as a part of this study group, you will be assigned a Taxi health Improvement Promoter, or TIP, and you will receive text message health and medical appointment reminders sent directly to your cell phone. Your assigned TIP is a NYC taxi driver, just like you, who is trained by our study team to work with you on scheduling, and on speaking with you about any necessary, medical appointments, and to help you to address other health concerns. Your TIP will check in with you weekly/monthly about taking care of general health needs and will remind you about setting up and keeping any medical appointments. Your contact with your TIP may be in person at the garage/enrollment site, at another convenient location, or over the phone.
  In addition to being connected with a TIP, you will also receive text messages sent to your cell phone while on study. All text messages will be sent by our study staff, not by your TIP. The text messages will include reminders about scheduling and going to any necessary medical

appointments, and we also provide weekly healthy living tips that are designed just for taxi drivers. If you do not have an unlimited text messaging plan, it is important to think about possible charges on your cell phone bill that you may get from the weekly healthy living and medical appointment reminder text messages that will be sent to your phone during this study.

Before the start of this study, we spoke with several taxi garages and sites frequented by drivers (e.g. airport holding lots, place of worship, etc.) that agreed to take part in this study. Each site was randomly put into one of three different study groups. This was assigned by a computer so that each site had an equal chance (like a flip of coin) of being assigned to any group.

Today you will be randomly assigned to one of the three groups based on which group your garage/enrollment site belongs to.

What extra tests and procedures will I have if I take part in this study?

Before you begin the study:

Study staff will ask you questions to see if you meet the study requirements and will share details about the study. You can ask questions about the study and we will try to answer all of your concerns. If you meet study requirement and you agree to join, you will be asked to sign this consent form.

During the study:

At the health fair, you will complete an intake survey that will ask questions about your background (e.g. driving history, household income), health care access, smoking habits, exercise and eating habits and medical history including cancer screening history. The study team will receive a copy of your Health Fair intake and will have access to your response for questions on your:

- Background (e.g. age, gender, country of birth, migration history)
- Health care access
- Workplace and earnings
- Medical history
- Health behaviors (e.g. smoking, diet)
- Stress

We will also receive a copy of your health measurements including:

- Height
- Weight
- Waist circumference
- Blood pressure

After finishing the intake form, you will be randomly assigned to one of the three study groups described below:

- Group 1 (Health Fair Only)
  We will test our usual health fair service; after drivers get free weight, height, waist, and blood pressure testing, our health fair staff will follow up with drivers who are told that they need to see a doctor due to a high blood pressure reading, or if they have any other unusual result that needs a physician follow-up.

- Group 2 (Health Fair + Navigation Case Management)
  In addition to the health fair services with general follow-up, you will be assigned a Navigator Case Manager who will work with you after the health fair to assist with setting up any needed medical appointments or additional health care needs. A Navigator Case Manage is one of our specially trained team members who has learned all about signing up for health insurance, how to use one's insurance card, and resources in NYC on where to get care. Our navigator case managers have experience with helping New Yorkers get insurance and finding a regular doctor. You will be connected to a navigator case manager who will work with you monthly to make sure that you get the information and support you need to make any necessary medical appointments and find a regular doctor that can work with you any health problems.
- Group 3 (Health Fair + TIP + mTECH)
  In addition to the health fair services with general follow-up, as a part of this study group, you will be assigned a Taxi health Improvement Promoter, or TIP, and you will receive text message health and medical appointment reminders sent directly to your cell phone. Your assigned TIP is a NYC taxi driver, just like you, who is trained by our study team to work with you on scheduling, and on speaking with you about any necessary, medical appointments, and to help you to address other health concerns. Your TIP will check in with you weekly/monthly about taking care of general health needs and will remind you about setting up and keeping any medical appointments. Your contact with your TIP may be in person at the garage/enrollment site, at another convenient location, or over the phone.
  In addition to being connected with a TIP, you will also receive text messages sent to your cell phone while on study. All text messages will be sent by our study staff, not by your TIP. The text messages will include reminders about scheduling and going to any necessary medical appointments, and we also provide weekly healthy living tips that are designed just for taxi drivers. If you do not have an unlimited text messaging plan, it is important to think about possible charges on our cell phone bill that you may get from the weekly healthy living and medical appointment reminder text messages that will be sent to your phone during this study.

If you choose to take part in the study, you will be asked to complete 3 surveys:
- 3 months after you begin the study (3 Month Follow-up)
- 6 months after you begin the study (6 Month Follow-up)
- At the end of the study, about 1 year after you begin (12 Month Follow-up)

At the 3 and 6 months mark, we will call you to set up a time to complete a brief follow-up survey that will take about 15-20 minutes to complete in person or on the phone. This survey will ask you questions about your health and use of healthcare.

At the 12-month mark, we will contact you again, to set up a time to complete a 1 year follow-up in person for about 15-20 minutes. We will meet with you in person at our office, or at your garage base/enrollment site, for follow-up. At this meeting, we will ask you the same survey questions on your health and use of healthcare and a trained staff member will take the same health measurements (height, weight, waist size, blood pressure) that you did at the first health fair. This study is approximately 12 months. In case we are unable to reach you, we will continue our efforts to reach you up until 6 months past your 12-month mark.

If you attend a medical appointment with a general doctor, we will also ask you to hand in any documentation of your appointments, which may include exit instructions, a doctor's note, explanation of benefits or payment receipt.

All surveys will be completed with you in your preferred language or a language that you speak well (English, Bengali, Urdu, Spanish, or French).

All information collected from you, including personal information, survey answers, and health measurements, will be linked to your study ID number only. Your name will not be linked to study data collected.

After you are finished with the study, the research team may contact you if any survey answer is unclear. If you agree, we may contact you in the future about other studies you might be interested in.

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

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss
- You may be stressed if you learn you have health problems or unmet clinical needs while participating in this study

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

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

- Keep your study appointments.
- Tell the study doctor about:
    - All medications and any supplements you are taking
    - Any side effects from these medications or supplements
    - Any doctor visits or hospital stays outside of this study
    - Whether you have been or are currently in another research study
- Let the study doctor know if you skip or chose not to answer any of the questions in the questionnaire/survey.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center.
This study is funded by National Institute of Nursing Research (division of NIH).

No conflicts of interest have been identified for either the institution or the investigator(s) in this study.

What are the costs of taking part in this study?

You will not be charged for taking part in this study. The service of the health fair and any counseling and health care access navigation given to you is provided at no charge.

You will be responsible for the costs of all texts and phone calls that you make or receive as part of participation in this study. The study will not pay for the costs associated with calls or texting. You may receive up to 2 healthy living text messages per week of study participation. The number of medical appointment reminder text messages will depend upon your medical appointment scheduling and may include up to 3 monthly reminder text messages to book a necessary medical appointment, 2 reminder text messages to attend a scheduled appointment, and 2 reminder text messages to find out if you attended the scheduled medical appointment.

In the event you have scheduled doctor appointments or are escorted to urgent care/emergency room, you and/or your health plan/insurance company will have to pay for the costs of these appointments, including the costs of any insurance co-pays and deductibles, as well as tests, or medical procedures that you may get as a results of seeing the doctor. The study team can work with you to find a low-cost doctor/health care options in your neighborhood.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

Ask the study doctor or nurse or the study staff for help finding the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

As a thank you, you will be receiving a total of $150 during the study period. You will receive $50 in cash or a gift card for completing the health fair intake, and for the 6- and 12-month follow-up surveys that you complete.

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

There is no risk of becoming injured or hurt from participating in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form. The study will not pay for medical treatment. We will work with you to find convenient, low-cost referrals if you need them.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de identified information from this study will be shared with other researchers outside of MSK. All requests for data sharing will be reviewed by MSK, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or social security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

In the future, your information (data) may be de-identified, which means that your data will be assigned a unique code, and the list that links the code to your name will be stored separately from your and data. Your de-identified information may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

The NIH has given this research study a Certificate of Confidentiality. This Certificate does not indicate that the NIH or the US Government recommends that you take part in this study. The Certificate helps us keep your health information private. Your records for this study include information that may identify you. The Certificate of Confidentiality lets us refuse demands to release your study records. The Certificate can be used in any federal, state, or local legal matter. The cases in which we cannot use the Certificate are explained below:

- To refuse a demand from the US Government for review of study records in the event of an audit of the research study
- To refuse a request for your study records if you or your legally authorized representative have given written permission for their release

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include any information that can identify you. At most, the web site will include a summary of the study results. You can search this web site at any time.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

Taxi HAILL: A Three-Arm Cluster Randomized Controlled Trial Examining Health Care Access Interventions for Taxi Drivers

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

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

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator(s): Dr. Francesca
- Gany, MD, MS and Dr. Jennifer Leng, MD, MPH
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- The company or organization that provides the funding for the study, National Institute of Nursing Research (division of NIH).
- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study procedure.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
    - Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

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

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to your medical record at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent
I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement
I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant/LAR signature		**Date:**
Participant/LAR name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____
(The name of the witness must be documented in the EMR.)

Interpreter (if required)
Name of interpreter (if present): _____
ID number (if phone interpreter): _____
(The interpreter's name or ID number must be documented in the EMR.)

The participant/Legally Authorized Representative must be provided with a **signed copy** of this form.