Memorial Sloan Kettering Cancer Center
IRB Number: 16-1659 A(13)
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Participant Informed Consent for Clinical Research

Study title for participants: Taxi STEP (Social networks, Technology, and Exercise through Pedometers)

Official study title for internet search on http://www.ClinicalTrials.gov:
Taxi STEP (Social networks, Technology, and Exercise through Pedometers)

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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 New York City taxi driver who attended a health fair at one of the garages, 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 to encourage drivers to increase their daily walking through the use of pedometers?

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 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 on increasing your physical activity. The study is built upon our health fairs service program. 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. We will also take your health measurements:

- Height
- Weight
- Waist circumference
- Blood pressure
- Cholesterol levels
- Blood sugar levels

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.

After participating in the health fair, you will be enrolled in the study and will be given a pedometer. Approximately, one month after the Health Fair, you will be randomly assigned to 1 of the 4 study groups:

- Group 1 (Health Fair and Pedometer only) - drivers participating in the health fair will receive a pedometer. Health fair staff will also follow-up with drivers who have high blood pressure readings or other unusual results to remind them to schedule a doctor's appointment or seek any service recommended at the health fair
- Group 2 (Health Fair, Pedometer + Text Messaging) - along with the pedometer and the regular health fair follow-up services described in Group 1, drivers will also receive daily text messages about walking and healthy lifestyles
- Group 3 (Health Fair, Pedometer + Social Network Support) – in addition to the pedometer and regular follow-ups in Group 1, drivers will receive a social network support guide to distribute among their friends and family members with whom they discuss important health matters.
- Group 4 (Health Fair, Pedometer + Text messaging + Social Network Support) – drivers in this group will receive the pedometer, the regular follow-up services, daily text messages and the social network guide for their friends and family.

Approximately 6 months after you are randomly assigned to a group, you will be called to complete a 30-minute follow-up survey. We will also schedule a time to meet with you in person to take your health measurements again. In the event that you are unable to meet in person for health measurements, we will accept self-reported measurements over the phone.

You will be in the study for about 24 months. In case, we are unable to reach you for the end of study assessment in 7 months, we will continue our efforts to reach you for 17 more months.

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.
- You may experience pain undergoing fingerstick blood draw (e.g. soreness at your fingertip) and may experience dizziness or light-headedness.
- 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 because you will be given a pedometer and may become more knowledgeable about exercise. Walking and exercise are very important to living a more active and healthful lifestyle and reducing health risks.

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.

We ask that you return the pedometer to a study staff member if you decide to stop taking part in the study before the end of the study.

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 Institutes of Health, 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 test the effectiveness of the four different approaches to encourage drivers to use a pedometer to increase their daily walking as pedometer-based walking programs have shown to help increase walking.

- Group 1 (Health Fair and Pedometer only)
- Group 2 (Health Fair, Pedometer + Text Messaging)
- Group 3 (Health Fair, Pedometer + Social Network Support)
- Group 4 (Health Fair, Pedometer + Text messaging + Social Network Support)

We have found that many taxi drivers are inactive and find it difficult to exercise because of their work hours. The lack of exercise puts many drivers at risk for heart disease, and perhaps, for cancer and walking is one of simplest ways to increase one's physical activity level and improve one's overall health. This study will thus help researchers find out which approach is the most effective way to increase walking among taxi drivers.

About 510 NYC taxi drivers people will take part in this study.

What are the study groups?

There are four study groups:

Group 1 (Health Fair and Pedometer only)

We will test our usual health fair services; drivers will get free weight, height, waist, and blood pressure testing. Our health fair staff will follow up with drivers who need to see a doctor due to a high blood pressure reading or other unusual result that needs a physician follow-up. All drivers will be given a pedometer with instructions on how to use it to track their daily step counts.

Group 2 (Health Fair, Pedometer + Text Messaging)

In addition to the health fair services with general follow-up, and giving each driver a pedometer with

instructions on how to use the device to track his daily step counts, all drivers in this group will receive

daily healthy living advice and encouraging messages about walking through text messages sent by our staff to drivers' cellular phones.

Group 3 (Health Fair, Pedometer + Social Network Support)

Each driver in this group will receive the health fair services with general follow-up along with a pedometer with instructions on how to use the device to track his daily step counts. Additionally, drivers in this group will be asked to provide the names of family or friends who will form a social support network team. This team will provide encouragement and remind participants to maintain a healthy lifestyle and increase daily walking activities. Social support networks can also participate in walking activities with the participant to increase motivation and practice healthy habits. Drivers will be given a social network guide to train their family and/or friends on how to best motivate the drivers.

Group 4 (Health Fair, Pedometer + Text messaging + Social Network Support)

Each driver in this group will receive the health fair service with general follow-up, along with a pedometer with instructions on how to use the device to track his daily step counts. They will also receive daily healthy living advice through encouraging text messages about walking through text messages sent by our staff to drivers' cellular phones. Drivers will also be asked to provide the names of family or friends who will form a social support network team. This team will provide encouragement and remind participants to maintain a healthy lifestyle and increase daily walking activities. Social support networks can also participate in walking activities with the participant to increase motivation and practice healthy habits. Drivers will be given tools to train their family and/or friends on how to best motivate the drivers.

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 your concerns. If you meet study requirements and you agree to join, you will be asked to sign a consent form.

During the study:

- At the Health Fair, you will be given a unique ID number, and complete an intake survey that will ask questions about your background and health (e.g. driving history, household income), health care access, smoking habits, exercise and eating habits and medical history including cancer screening history. You will also
    - complete a series of heath measurements (height, weight, waist circumference, blood pressure, blood cholesterol levels, and blood sugar levels)
    - discuss your results with a doctor or a nurse and we may have given you advice about low cost health care options in your neighborhood.

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
- Cancer Screenings
- Health behaviors (e.g. smoking, exercise)

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

- Height
- Weight
- Waist circumference
- Blood pressure
- Cholesterol levels
- Blood sugar levels

In addition, we will obtain a copy of the advice given to you by the doctor or nurse at the end of the Health Fair. Approximately one month after the Health Fair, you will be randomly assigned to 1 of the 4 study groups, like a flip of a coin; this means you will have an equal chance in being in any of the groups. A study staff member will tell you which group you will be a part of and when it will start. We will meet you in person or contact you by phone to have this discussion at a convenient time and location. A study staff member
will be available to answer any questions you might have.

You will be randomly assigned to one of the four groups described below:

- **Group 1- Health Fairs Service with Pedometer**. This group will include the regular health fair follow-up process (our health fair staff will follow up with drivers who need to see a doctor due to a high blood pressure reading or other unusual result that needs a physician follow-up). Health fair staff will contact you within 2 weeks after the health fair to remind you to schedule a doctor's appointment or seek any service recommended to you at the health fair. Calls will be made to you in either English, French, Bengali, Spanish or Hindi (as per your preference). Health fair staff will also assist with getting insurance if needed. If you don't schedule recommended medical appointments, health fair staff will ask for reasons why.
- Additionally, all drivers will receive a pedometer, and our staff will go over how to use the pedometer to track your daily step counts. The pedometer will be linked to a previously created online user account. To track your daily step counts, your height and weight will be entered into the account. We will share your username and password with you so both you and our study team will be able to access your account to see how much you have been walking. You will be asked to connect your pedometer device to your online user account at least once a week to upload your step counts. Study staff can address any questions or issues you may have with your pedometer during the study. They can also meet with you in person, if needed, to connect your pedometer with your account. Our study team will use a special computer program to find out if there are any changes in your physical activity level while on the study.

OR

- You may be assigned to **Group 2- Health Fair, Pedometer + Text messaging** Along with the regular health fair follow-up services, you will receive a pedometer, as discussed above under Group 1. This group will also receive daily text messages to encourage walking and to provide

tips on maintaining an overall healthy lifestyle. All texts will be sent while you are off duty, to avoid any distractions while driving.

OR

- You may be assigned to **Group 3-Health fairs, Pedometer + Social Network Support**. Along with the regular health fair follow-up services, you will receive a pedometer, as discussed above under Group 1. Additionally, each driver in group 3 will be asked to select individuals in their circle of family and friends with whom they discuss important health matters; they will be a part of your social network support team. You should think of these select family members and friends as a special buddy to encourage you with a healthy lifestyle change. This team will encourage and remind you to get more exercise and lead a healthier life. The study staff will give the drivers in this group a social network support guide that will help you train your social network support team to effectively encourage and support you. It is up to you who you select to be a part of your social network support team. If you do not want to provide us with any names, you can still participate in the study.

OR

- You may be assigned to **Group 4-Health fairs, Pedometer + Text Messaging + Social Network Support.** Along with the standard health fair follow-up services, you will receive a pedometer, as discussed above under Group 1. Participants will also receive daily text messages to encourage walking and provide tips on maintaining an overall healthy lifestyle. All texts will be sent while you are off duty, to avoid any distractions while driving. Each driver in group 4 will also be asked to identify the people in their circle of family and friends with whom they discuss important health matters; they will be a part of your social network support team. You should think of these select family members and friends as a special buddy to encourage you with a healthy lifestyle change. This team will encourage and remind you to get more exercise and lead a healthier life. The study staff will give the drivers in this group a social network support guide that will help you train your social network support team to effectively encourage and support you. It is up to you who you select to be a part of your social network support team. If you do not want to provide us with any names, you can still participate in the study.

Approximately six months after you are randomly assigned to a group:

We will call you to set up a time to complete a follow-up survey in a one-on-one interview format, just like you did during the health fair. This will take approximately 30 minutes to complete. We can complete the follow-up survey with you either in person or over the phone. This survey will ask you similar questions to the survey you completed at the health fair, including:

- Health care access
- Workplace and earnings
- Medical history
- Cancer Screenings
- Health behaviors (e.g. smoking, exercise)

We will ask to schedule a time to meet you in person to repeat health screening measurements previously conducted at the health fair. This will include:

- Height

- Weight
- Waist circumference

- Blood pressure
- Cholesterol levels
- Blood sugar levels

Additionally, as described above, we will have access to your daily step count through your pedometer account and you will be expected to connect your device to your online account at least once a week.

You will be in the study for about 24 months. In case, we are unable to reach you for the end of study assessment in 7 months, we will continue our efforts to reach you for 17 more months.

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 side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it difficult for you to have children.
- Some side effects may be mild. Others may be very serious, and may even result in death.

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.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce your side effects.

Please note that under New York State law you cannot use a handheld mobile telephone while you drive. Along with making and receiving calls, illegal activities include composing, sending or reading text messages. Your safety is important to us, and every effort will be made to send all healthy living text messages during your non-work hours. Please make sure to let the study team know if you work hours change during your time on the study.

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?

The study sponsor is Memorial Sloan Kettering Cancer Center.
The study is funded by the National Institutes of Health.
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 the pedometer are provided at no charge.

If you are randomly assigned to group 2 or 4, the group that receives mobile health text messaging, you will be responsible for the costs of all texts that you make or receive as part of participation in this study. The study will not pay for the costs associated with receiving text messages on your cell phone. You will receive 1 healthy living text message daily for the 6 months of study participation.

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 $100 for taking part in the study ($50 one month after the health fair and $50 at the end of the study). You will be allowed to keep the pedometer provided to you as a thank you for your study participation.

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 in this study, call the Memorial Sloan Kettering Cancer Center Institutional Review Board (IRB) at 212-639-7592. Jorge Capote, RN, is MSK's Patient Representative; you may call him if you have concerns, complaints, or input on research, or for more information about the consent process, at 212-639-8254.

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

Taxi STEP (Social networks, Technology, and Exercise through Pedometers)

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
- 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, the National Institutes of Health.
- 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 the National Institutes of Health, 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.

Memorial Sloan Kettering Cancer Center
IRB Number: 16-1659 A(13)
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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.