**Example Standardized Language Elements:**

**Non-Biomedical Research Consent Form**

***THIS DOCUMENT****: is a companion document to the non-biomedical research* ***Consent Form Template****. It provides IRB-reviewed and approvable example standardized language that can be cut and pasted into the Consent Form Template. Opening standard language for each section below is already included in the Consent Form Template for Non-biomedical Research. The standard language text included in this document can be added if applicable. For all sections that do not include standard language text, please refer to the Consent Form Template for Non-biomedical Research for required language. To download a copy of the Consent Form Template for developing a biomedical consent form, please go to* [***Research Protocol Development & Guidance Tools***](https://med.nyu.edu/research/office-science-research/clinical-research/resources-researchers-study-teams/institutional-review-board-operations/irb-template-library)

***BLUE TEXT****: represents guidance language on the use of the standardized language text provided by this document.*

**BLACK TEXT***: represents example standardized language text. The standardized language text is presented under the applicable numbered consent section to make it easier to cut and paste from this document into the Consent Form Template.*

***RED TEXT:*** *Indicates sections where there is a requirement for the use of the specific standard language text—and is therefore already included in the Consent Form Template noted above. These required standard language elements have also been reviewed and approved by the Office of General Counsel.*

1. About volunteering for this research study

*[****Cognitive Impairment****: For studies enrolling subjects who are cognitively impaired]*

Some of the people who may be able to take part in this study may not be able to give consent because of their medical condition. In this case, we will ask the person’s authorized representative, called their Legal Authorized Representative, to give consent for them. However, throughout the consent form, “you” always refers to the “subject” or person who takes part in the study.

*[****NYU Langone Health Employees and/or Students as Research Subjects:*** *Use the following sentences as applicable when your study enrolls NYU Langone Health Employees or Students:]*

*[For NYU Langone Health Employees, add the following:]*

As an NYU Langone Health employee, your decision to participate, decline, or withdraw will have no impact on your employment, salary, or performance evaluation.

*[For NYU Langone Health Students, add the following:]*

As an NYU Langone Health student, your decision to participate, decline, or withdraw will have no impact on your grades or academic standing. Participation cannot be linked to an academic record.

1. **What is the purpose of the research study?**

The purpose of this research study is to *[Describe the* ***purpose******or research objectives from the protocol*** *in non-medical terms and at an 8th grade reading level].*

We are asking you to take part in this research study because you have a medical condition being studied and/or are scheduled to have test/procedure. *[Provide brief description of the medical condition being studied.]*

This research study is being done to collect your thoughts/reactions/opinions. We will do this through a Survey/Questionnaire/Focus Group/etc.

*[Use the following language for explanation of different types of study designs.]*

*[For healthy volunteers]*

You qualify for this study because you are a healthy volunteer.

*[For randomized study design]*

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the treatment groups and receive *[explain to subjects what they may receive]*. There are no special requirements or criteria to be in either group. You will have an *[explain to subject their chances of receiving either treatment].*

*[For comparison study design]*

This research study will compare *[fill in]* to the standard of care. Standard of care is the first choice of treatment for your disease or condition.

*[For Genetic Research Testing]*

*If genetic research will be performed, briefly explain DNA and genes when they are mentioned for the first time. See suggested language below:*

We plan to do genetic research on the DNA in your tissue sample. DNA is the material that makes up your genes. All living things are made of cells. Genes are the part of cells that contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are passed from parent to child.

*If cell lines will be created, include the sentence below:*

Your tissue sample may be used to create a living tissue sample (called a “cell line”) that can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

*If iPS cells will be created, include the paragraph below. If cells will be used in animal models, include the last sentence, as well.*

We may use the cells taken from your [specify source of cells, e.g. skin] to create a type of cell known as a pluripotent cell. This type of cell can be used to create different types of tissue, including [specify type of cells, e.g. cardiac, muscle, etc.] cells. Your cells might be used in research involving genetic alteration of the cells. Your cells might be mixed with other human cells, mixed with animal cells, or grown in lab animals like mice.

*If GWAS (genome-wide association studies) or large-scale gene sequencing may be performed, include the following paragraph. Modify the information below to reflect whether the GWAS/sequencing data and/or samples will be restricted to the disease under study and related research, or can be used for unrelated research.*

We may also perform a whole genome analysis on your DNA sample. Usually, researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to *[signify here whether the GWAS/sequencing data will be limited to the disease under study and related disorders or "many diseases or conditions"].*

*If the tissue/data will be sent to NIH or other tissue/data repositories, include the paragraph below:*

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store **DNA samples**, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

*Delete the paragraph below if the tissue/data will only be used for the condition under study and research related to that condition.*

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease.

1. How long will I be in the study? How many other people will be in the study?

This study will last about *[# of days, months, years]* and will involve about *[# of visits]*.

About *[state projected #]* study subjects between the ages of *[X and Y]* are to be entered into this study across all sites. About *[state projected #]* study subjects from NYU Langone Health are to be entered into the study.

*[If single-center, state the number of subjects participating in the study.*

*If multicenter, state that fact, list the number of centers and the approximate total number of participants that will be participating at NYU Langone Health* ***(optional).*** *Otherwise, state the total number of subjects participating in the study at all sites.]* **[NOTE TO RESEARCHERS: You may choose not to include the specific number of subjects at NYU Langone Health if NYU Langone Health is one of the sites of a multi-center study. This will allow you to minimize the number of required modifications to the consent form.]**

*[Keep one of the following phrases; delete the rest (as appropriate).]*

This study will be an in-patient study. This means the study will happen only while you are in the hospital.

This study will be an out-patient study. Your study visits will be at *location*.

This study will be both an in-patient and an out-patient study. This means the study will happen while you are in the hospital. Other study visits will be at *location* as an outpatient.

1. What will I be asked to do in the study?

In this study, you will be asked *[describe task, surveys, interviews or procedures].*

You will be assigned to an experimental/control group *[include this sentence only when applicable].*

Your participation in this study will last for *[insert # of hours, days, and months]* and will involve number of visits/sessions at *[insert the location].* We will schedule them at a time that is convenient for you.

*[If the study involves surveys or questionnaires, include:*

You are free to skip any questions that you prefer not to answer.

*[If consenting will occur prior to the initial study visit you can add the following:]*

As a participant in this study, you will be asked to come to [insert location].

*[If audio recording is optional, insert “I agree”… and “I do not agree…” options at the end of the form.]*

We will conduct this interview in a location of your choice and at a time of your choosing. We will audio record this interview and take detailed notes afterward. We will do so only with your permission. You have the right to review and edit the recording to delete any material you do not want recorded. You may also ask us to turn off the recorder at any point in the conversation.

*Or*

I will conduct the interview in your home, in an agreed-on location or over the telephone. I will audio record the interview so I can remember what you said. I will only do so with your permission. If you do not wish to be audio recorded it will not be possible for you to be in the study.

*[If enrolling NYU Langone Health Employees and/or Students, add the following:]*

The study procedures will be conducted at *[specify location]*.

*[The “I agree...” “I do not agree...” options for recording are not needed if recording is required for participation and this is clearly stated on this form.]*

*[If audio recording is not optional, clearly state that it is required for participation.]*

Audio and / or video recording are required for participation. If you do not wish to be recorded, you cannot participate in this study.

*[Describe how the post audio/visual recording options]*

After the interview, the recording will be transcribed and a written copy will be sent to you for review. You may delete anything you do not want included in the interview.

*Or*

We will contact you in six months to see if you feel differently after the passage of time about the event you described when your feelings were hurt.

*[Describe the procedures for discontinuation of a subject's participation, including the right to withdraw data already collected, if applicable.]*

At any time in the study, you may decide to withdraw from the study. If you withdraw, no more information will be collected from you. When you indicate you wish to withdraw the investigator will ask if the information already collected from you can be used.

If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.

Each visit is listed separately and identified by visit number. Included in this visit list, will be the research procedures done to the subject, the amount of time the subject will be at the visit, and any other relevant information pertaining to that individual study visit. The list provided is a general list. This is to be tailored specifically to your individual protocol. Repeat each visit with a list of all procedures study-related. You may use a table but the contents of that table must be relevant and in non-scientific terms.

Below is a list of each study visit that is part of the study. This list includes about how long each visit should take and a list of the research tests and procedures to be done at each visit and/or blood work to be taken. This section will help you understand what is expected of you at each visit.

**Visit 1: Your Screening Visit**

This visit takes about *[describe time interval]*. During this visit, we will do some tests and procedures to see if you meet the requirements to take part in the study. The study doctor will review the results of these tests and procedures. If you do not meet the requirements, the study doctor will tell you why.

At this visit, we will:

Ask you about your medical history

Ask you what medications you take – including over-the-counter and prescription medications, vitamins or herbal supplements.

Give you a physical exam, including height, weight and “vital signs” (blood pressure, temperature, heart and breathing rates)

Take a blood sample. We will insert a needle into your arm and take a small tube or vial of your blood (about *[x]* teaspoons). *[If Fasting Blood work include]* It is important that you DO NOT have anything to eat or drink (except water) for 8 hours before you come for this appointment. This includes candy and gum.

Ask you for a urine sample. We will test your urine for:

* + certain drugs including illegal drugs. (See next section called Urine Drug Screen).
	+ *[Include if applicable:]* Your blood will also be checked to see if you are pregnant. You may not take part in this study if you are pregnant.

Perform an EKG (electrocardiogram) to check the electrical activity of your heart.

Perform a chest X-ray

Ask you to complete some forms about your *[select all that apply:]* general health and well-being, quality of life (if you are happy about your life), mental health, emotional health, mood and memory.

Urine Drug Screen

During the study, we will test your urine for drugs, including illegal drugs like *cocaine, amphetamines and others (for multisite studies or studies taking place outside New York, please confirm local laws).* If your urine shows you have taken any of these drugs, you cannot be in the study. The results of the urine test will NOT become part of your medical record. These test results WILL become part of your research record.

*Customize the Visit Section similar to the Screening Visit. All procedures are to be listed here and repeated for each study visit. Keep sentences short and use non-medical terminology. Use bullet points. Keep visits in chronological order. Include approximate time of each visit. Include amount of blood to be drawn at each visit using tsp. consistently throughout the consent. Be sure to include what is expected of the subject at the final study visit.*

*[****Blood sample****: Include the following for studies with blood sampling]*

**Blood Samples**

We will take blood samples every *[specify time interval]*. There will be about *[number]* blood samples taken altogether. The total amount of blood drawn will be about *[number]* teaspoons during the entire study. A standard blood donation is about 96 tsps or about 2 cups.

After you complete the study, you will go back to your own doctor for your ongoing medical care. The study doctor will not be able to continue providing your medical care.

*[****Whole Genome Sequencing:*** *Include the following statement if research procedures includes the collection of biospecimens for the purpose of whole genome sequencing]*

The research *[choose one:* ***will*** *or* ***may****]* include whole genome sequencing (i.e., looking at entire DNA to identify any changes).

***[Communicating with the Research Team via Text Message:*** *Include the following statement if protocol permits you to contact subjects via text message for study related communications]*

Researchers may be need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given the Researchers your email address and mobile/cell phone number and permission to send a text message, the research team may contact you that way.  When the research team sends email messages that include identifiable health information, they will use encrypted messaging (e.g. sendsafe). When the research team uses texting over mobile/cell phones there is no way to encrypt the message. This means that information you send or receive by text message is unencrypted and could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Therefore, text messages carry security and privacy risks.

Below are some important points about texting in this research study.

* Text messages are not encrypted, and therefore are unsecure and may result in a breach of your confidentiality.
* You will be responsible for all fees charged by your carrier’s service plan for text messaging.  This research study and NAME OF SITE will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts
* Text messages will only be read during regular business hours. However, if you have a scheduled visit outside of business hours, you may receive a text in relation to this visit outside of regular business hours.
* Text messaging should not be used in case of an emergency.  If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
* You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says “Stop Research Text.”
* Your agreement applies to this research study only.  Agreeing to other texts from NAME OF SITE, for example appointment reminders, is a separate process.  Opting out of other texts from NAME OF SITE is a separate process as well.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

\_\_\_\_\_\_ Yes, I agree to receive texts from this research group. \_\_\_\_\_\_\_\_ Initial here        Cell phone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

     \_\_\_\_No, I do not agree to receive texts from this research group. \_\_\_\_\_\_ Initial here

1. What are the possible risks or discomforts?

There may be some risk from being in this study *[Describe the risks—psychological, emotional, physical, legal, privacy issues, etc. Depending on the type of study, some risks may be better described as things that could make the subject “uncomfortable” –such a fatigue or embarrassment. There is no such thing as a “risk free” study. If there are no known risks, state that there are “no foreseeable risks” to participating]*

*Describe or list additional counseling or support services for studies that may engender strong emotions.*

*Example:*

You may experience frustration that is often experienced when completing surveys. Some questions may be of a sensitive nature, and you may therefore become upset as a result. However, such risks are not viewed as being in excess of “minimal risk”

If, however, you become upset by questions, you may stop at any time or choose not to answer a question. If you would like to talk to someone about your feelings about this study, you are encouraged to contact, *[if appropriate add in hotline numbers, agencies or another service if appropriate].*

*[Unforeseen Risks: In addition to anticipated/expected risks, certain studies may involve unforeseen reactions, hazards, discomforts, and inconveniences affecting the quality of life. If you anticipate unforeseen risks, a statement must be included that* "participation in the study may involve unforeseen risks". *Where possible, list such risks, indicate what will be done to avoid or minimize such unforeseen risks.]*

*If the research involves women of child bearing potential, and the risks of the interventions to the embryo or fetus are not well known [not needed if the interventions present no additional risk to a fetus or embryo]* add “If you become pregnant during the research, there may be unknown risks to the embryo or fetus, or risks to the embryo or fetus that we did not anticipate.”

*Do not use medical terminology to describe side effects – refer to IRB Glossary of Terms to assist you. All risks must be explained at an 8th grade level (or lower).*

### Side Effect of Having Blood Taken

* Fainting or feeling faint. Tell the study staff right away if you feel faint.
* Redness, pain, bruising, bleeding or infection at the needle site.

***[Radiation Risk:*** *include this section if the diagnostic imaging is being done for research related purposes only. If the testing is part of standard care and would be completed whether or not the participant agrees to be in the study, then this section should not be added.*

*[Add research related to this section]*

**Radiation Risk related to Diagnostic Imaging**

Your participation in this research study will involve exposure to radiation from *[include diagnostic imaging type i.e. PET scans, CT scans, etc.].* This radiation exposure is not necessary for your standard medical care. These scans are for research purposes only and will be*additional*radiation exposure. If you wish to avoid this additional radiation exposure, you should not participate in the study.

*[Include standard language relevant to dose:]*

*[Include the following statement if the* ***effective dose will be under 3 mSv:]***

The effective radiation dose you will receive from these research scans is approximately *[insert amount]* mSv (mSv is a unit of effective radiation dose, or a measure of the long-term risks of cancer). This amount is less than the annual radiation exposure that you receive from the natural environment, which is 3.1 mSv in the U.S. It is also much less than the annual limit set by the FDA for individuals participating in basic research studies, which is 50mSv. According to the International Commission on Radiological Protection (ICRP), the increased risk of health effects, such as cancer, from the radiation exposure you will receive in this study is too small to be easily measured.

*[Include the following statement if the* ***effective dose will be from 3 to 50 mSv:]***

The effective radiation dose you will receive each year from these research scans is approximately *[insert amount]* mSv (mSv is a unit of effective radiation dose, or a measure of the long-term risks of cancer). This amount is within the annual limit of 50 mSv set by the FDA for individuals participating in basic research studies. You should note that this is in addition to any radiation exposure that you may undergo from your standard medical care. The total effective dose you will receive from all combined research scans in this study is approximately *[insert amount]* mSv. The organ receiving the highest radiation dose in this study is the *[insert organ].*

Exposure to high doses of radiation is known to increase the risk of cancer. The radiation dose you will receive in this study is relatively low by comparison. The risks to humans of low doses of radiation are not well known. The International Commission on Radiological Protection (ICRP) assumes that smaller doses of radiation result in proportionally smaller risks of cancer. Under this assumption, your increased risk of cancer from participating in this study is less than 0.2%.

*[Include the following statement if the* ***effective dose will be from >50 to 100mSv]***

The effective radiation dose you will receive each year from these research scans is approximately [insert amount] mSv (mSv is a unit of effective radiation dose, or a measure of the long-term risks of cancer). You should note that this is *in addition* to any radiation exposure that you may undergo from your standard medical care, such as CT, SPECT, PET, cardiac catheterization, interventional radiology or radiation therapy. The total effective dose you will receive from all combined research scans is approximately [insert amount] mSv. The organ receiving the highest radiation dose in this study is the [insert organ].

Exposure to high doses of radiation is known to increase the risk of cancer. According to the International Commission on Radiological Protection (ICRP), the increased risk of health effects, such as cancer, from the total radiation dose you will receive in this study is approximately [0.0041 x (total mSv in study)] %.

Your risk of cancer may be increased if you have undergone certain procedures as part of your standard medical care. You may wish to consult your doctor to determine whether you have been exposed to radiation as part of your standard medical care, and what radiation dose you received.

*[Include the following statement if the* ***effective dose will be from >100 mSv]***

The scans you will undergo in this study will expose you to a significant amount of radiation. The effective radiation dose you will receive each year from these research scans is approximately *[insert amount]* mSv (mSv is a unit of effective radiation dose, or a measure of the long-term risks of cancer). This is *in addition* to any radiation exposure that you may undergo from your standard medical care, such as CT, SPECT, PET, cardiac catheterization, interventional radiology or radiation therapy. The total effective dose you will receive from all combined research scans is approximately *[insert amount]* mSv. The organ receiving the highest radiation dose in this study is the *[insert organ].*

Scientists believe that exposure to this amount of radiation can increase your risk of cancer and/or leukemia. According to the International Commission on Radiological Protection (ICRP), the increased risk of health effects, such as cancer, from radiation doses of this amount is approximately *[0.0041 x (total mSv in study)]* %.

Your risk of cancer may be further increased if you have undergone certain procedures as part of your standard medical care. You may wish to consult your doctor to determine whether you have been exposed to radiation as part of your standard medical care, and what radiation dose you received.

***[Add the Following for Brain or Heart Dose > 500 mGy:]***

The total absorbed dose to the [insert brain and/or heart] for this study may be [insert amount] mGy (mGy is a unit of effective radiation dose to a specific organ).The ICRP believes that absorbed doses to the [insert brain and/or heart] greater than 500 mGy have the potential to cause circulatory disease

***[Radiation Risk:*** *include this section of the diagnostic imaging is being done for research related purposes only. If the testing is part of standard care and would be completed whether or not the participant agrees to be in the study, then this section should not be added.]*

The NYULH Radiation Safety Committee has reviewed the use of diagnostic radiation in this research study and determined the study may proceed with this level of radiation. Please inform the investigator if you have been exposed to radiation as a result of any other research studies or as part of your clinical care. If you participate in future studies that involve the use of radiation, you should inform the researchers performing those studies that you have already been exposed to *[insert amount*] mSv in this study.

Pregnant Subjects:

You cannot participate in this study if you are pregnant or breastfeeding. That is because fetuses and infants are particularly sensitive to radiation. Women of child-bearing potential must have a negative pregnancy test before they can have *[state the names of all scans in this study using ionizing radiation]*. It is important to understand that a pregnancy test may give a negative result even if you are pregnant, depending on the timing of the test relative to ovulation.

### Electrocardiogram (EKG)

The EKG test is a recording of the electrical activity of your heart and an EKG is harmless. The sticky pads (electrodes) that are placed on your chest can sometimes cause discomfort such as redness or itching. We may need to shave your chest before we attach these pads. Irritation from shaving also may occur.

### Magnetic Resonance Imaging (MRI)

MRI uses strong magnetic fields and radio waves to make images of the inside of your body. MRI does NOT involve high-energy radiation (like X-rays). For most people MRI is very safe. However, if you have anything made of metal on your skin or inside your body, MRI may not be safe for you, and you must tell study personnel before your scan. Also, if you have any electronic devices on the outside or inside of your body, you must tell study personnel about those too. Some things, like tattoos, may have metal materials in them even though you might not realize it. For this reason, study personnel will give you a checklist of things that have metal or electronic parts in them. You must read the list carefully before your scan and put a checkmark next to everything that applies to you.

The following paragraphs will describe the possible risks of MRI. To reduce many of these risks, you will be given an emergency squeeze ball to hold in your hand during the scan. If you feel any discomfort you should squeeze the ball. This sets off an alarm that the technologist can hear. The technologist will then talk to you, and will stop the scan if you want. There is a microphone in the scanner so that you can communicate with the technologist. However, the scanner makes a lot of noise when it is running and the technologist may not always hear what you say. If you need to get the technologist’s attention, you should squeeze the ball.

Remember, if at any point you feel uncomfortable and want to stop the scan, just squeeze the ball and tell the technologist.

**Risks from metal**

The strong magnetic field in the scanner will pull on things that contain certain types of metal. If someone takes a metal object into the scan room, it might fly towards the scanner and hurt you. For this reason, everyone (including you) must remove everything metal from their clothes and pockets before going into the scan room. Also, the door to the scan room will be kept closed during the scan to prevent unauthorized people from walking in.

If you have something metal inside your body, the scanner might pull on it and make it move. You must tell study personnel before your scan if you have anything metal inside your body.

Some types of metal might heat up when the scanner is running. If you feel any burning sensation during the scan, you should squeeze the emergency ball and the technologist will stop the scan.

**Risks from electronic devices**

If you have any electronic devices on the inside or outside of your body, the scanner might make them stop working properly. For this reason, you must tell study personnel before your scan if you have anything electronic on or in your body.

**Burns**

Metal is not the only thing that can cause burns in MRI. It’s possible (although very rare) to get burned by touching the inside walls of the scanner or by making skin-to-skin contact. The technologist will give you a blanket or cushions so that you don’t touch the inside walls of the scanner. You should also avoid letting your hands or legs touch each other. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the technologist will stop the scan.

**Tinnitus (ringing in the ears) and hearing loss**

The scanner makes very loud sounds while it is running. You will be given earplugs or headphones to wear during the scan. Make sure you roll the earplugs tightly and let them expand in your ears so that they work properly. If the sound of the scanner is still so loud that it causes you discomfort, squeeze the emergency ball and tell the technologist. This is important because very loud sounds can cause ringing in the ears or even hearing loss.

**Feeling warm or hot**

The radio waves used in MRI are like those your cellphone uses, but much stronger. Sometimes they are strong enough to make you feel warm (just like standing in bright sunshine makes you feel warm). MRI scanners are designed to try to avoid you getting too hot. However, if you start to feel uncomfortable, squeeze the emergency ball and tell the technologist.

**Peripheral nerve stimulation (tingling or twitching)**

The magnetic field inside the scanner changes very quickly while the scanner is running. If it changes too quickly, it can give you tingling sensations or make you twitch. MRI scanners are designed to try to avoid this. However, if you experience tingling or twitching, squeeze the emergency ball and tell the technologist.

**Claustrophobia (discomfort in enclosed spaces)**

Some people get panic attacks inside enclosed spaces. This is called ‘claustrophobia’, which means ‘fear of confined spaces’. If you know that you are claustrophobic, tell study personnel before your scan. Some people only find out they are claustrophobic when they have an MRI for the first time. If you feel anxious or panicky inside the scanner, squeeze the emergency ball and the technologist will get you out.

**Quench**

In very rare circumstances, the scanner can lose its magnetic field. This happens very suddenly and is known as a ‘quench’. The helium that helps keep the magnetic field strong will then escape from the scanner. The scanner is connected to a vent so that the helium will go outside the building. However, if for some reason the vent doesn’t work properly, helium might fill the scan room, making it difficult to breathe. In the very unlikely event of a quench, the technologists will get you out of the scanner immediately.

ADDITIONAL LANGUAGE:

**FOR STUDIES REQUIRING GADOLINIUM CONTRAST (MRI DYE)** <- [*Include only for studies that require contrast]*

You might need to have an injection of gadolinium contrast (a dye that lights up on the images). Sometimes the dye can cause side effects like headache, dizziness, or nausea (feeling slightly sick) for a short time after the injection. Some people might get an itchy skin rash, although this is uncommon (about 1 in 1000 people). It is also possible to have a serious allergic reaction called ‘anaphylactic shock’, which can cause swelling of the mouth and make it difficult to breathe. However, this is very rare (about 1 in 10,000 people). The technologist will tell you ahead of time when the dye is about to be injected, and will keep in contact with you to make sure that you’re OK. If you feel any discomfort, squeeze the emergency ball and the technologist will come into the room to check on you.

The dye leaves your body in your pee. Provided your kidneys are healthy, it should be almost all gone in about 24 hours. However, if you have kidney problems, you should tell study personnel before your scan. In rare situations, people with severe kidney problems have developed a serious condition called ‘nephrogenic systemic fibrosis’ from certain types of dye.

Fairly recently (in 2014) scientists discovered that if people get many injections of certain types of dye, some of the dye seems to stay in their brain for a long time afterwards. Doctors don’t know yet whether this is bad for you or not. However, if you have already had dye many times before, you should tell study personnel before your scan.

**FOR STUDIES REQUIRING EXTERNAL LEAD PLACEMENT (e.g., Cardiac MRI):**

Wires placed on the body during a scan can result in warming and in some cases the potential for burns. If cardiac monitoring wires are required during the scan, the operator is trained to inspect and arrange them to minimize this risk.

### FDG-PET/CT Scan

A small amount of radioactive sugar will be injected (shot) into your blood through a vein in your arm about 1 hour before the scan. You should not feel any effects from the sugar as it is a small, safe amount of radioactive material. There is a small risk of allergic reaction to the radioactive material and there is always a slight risk from being exposed to any radiation. You may have swelling, soreness, or infection at the injection site. The radioactive material is passed out of the body through the urine (pee) within 24 hours after the test is completed.

You will need to lie still for up to 1 hour in the PET/CT scanner. You will have a brief CT scan that takes about a minute followed by the PET imaging that takes between 25 and 45 minutes. If you know that closed spaces make you anxious, speak to the study staff before the PET/CT scan. You may be able to take medication to help you relax. You will be exposed to some radiation during the scan. Each PET/CT gives off about as much radiation as you would be exposed to from the earth and the sun in 4 – 5 years. There is always a slight risk from being exposed to any radiation. If you become anxious or uncomfortable during the PET/CT, tell the study staff or technologist and they will stop the PET/CT right away.

### Bone Scan

A dose of radioactive material will be injected (shot) into a vein in your arm. You should not feel any effects from the injection, as it is a small, safe amount of radioactive material. You may develop swelling, soreness or infection at the injection site. After 2 – 3 hours, you will be asked to lie down on a flat table and a special camera will pass over your body. The scan will take about 45 – 60 minutes once you are on the table. If you know that closed spaces make you anxious, speak to the study staff before the test starts. You may be able to take medication to help you relax. There is a small risk of allergic reaction to the radioactive material and there is always a slight risk from being exposed to any radiation. Each bone scan gives off about as much radiation as you would be exposed to from the earth and sun in 6 months. If you become anxious or uncomfortable during the Bone Scan, tell the study staff or technologist and they will stop the Bone Scan right away.

### Echocardiogram

The sticky pads (electrodes) that are placed on your chest may cause discomfort such as redness or itching. If we need to shave your chest before we attach the pads, irritation from shaving may also occur. You may feel slight pressure from the transducer or probe that the technician rubs across your chest. You may be asked to breathe, hold your breath or to lie in a position that may be uncomfortable during the test.

**Whole Genome Sequencing**

Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes, stigmatize, or discriminate against members of a socially defined group such as race or ethnicity; which could impact employability as well as marital, adoption, and child-custody opportunities.

**Return of Incidental Genetic Findings**

If you choose to be told about incidental findings discovered through this research, there can be a risk in knowing the results of incidental findings discovered through the course of this research. New health information about inherited traits that might affect you or your family could be found during a research study. Even without your name or other identifiers, your genetic information is unique to you. We will remove your name and other identifiers from your sample and personal health information, and replace them with a code number. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. You also share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low.

Genetic testing can also generate information about your personal health risks and can cause or increase anxiety, damage family relationships, and/or compromise insurability, employability and can even lead to discrimination. Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.

A Federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for certain employers and employer-based health insurance companies and group health plans to discriminate against you based on your genetic information. GINA also limits the organizations from sharing your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease. Health insurance companies and group health plans may not request your genetic information from this research and the Sponsor will not share this information with such companies, plans or employers.

1. What if new information becomes available?

*[Insert language as required for your individual protocol.]*

Any clinically relevant information derived from this research *[Choose one:* ***will*** *or* ***will not]*** be shared.

*If you do not intend to share, explain the reason why (results are not validated, no clinical impact, etc).*

*If you intend to share, include the circumstance in which the information would be disseminated to subjects, and include the following as appropriate:*

**Incidental Findings for Genetic Research:**

In this section, we are asking you to indicate whether or not you would like to know about any incidental findings. During the course of this study, we may incidentally find something on a part of your genome that’s known to be associated with a certain disease or condition. The study doctor will evaluate this finding to determine whether or not there is any clinical impact on you or your family. The Principal Investigator or another clinician on the study may also perform the test again in a certified laboratory to confirm if the finding is correct. If the finding is determined to have a possible clinical significance, the Principal Investigator or another clinician on the study will speak to you in person or on the telephone regarding the new information.

If you would like to know about any incidental findings, it is important for you to know that when the PI or clinician perform tests in a certified laboratory, results will also be included in your medical record, which means that anybody authorized to see your medical record (i.e. your treating doctor) will have access to this information.

It is possible that you may have a condition or genetic predisposition that we do not come across as part of this research. If you would like a comprehensive review of your genetic information, we recommend that you undergo further validated genetic testing and seek genetic counseling.

Below we are asking you to indicate whether or not you would like to know about any incidental findings as described above. Please initial one of the options below to confirm whether you would like to be informed of any incidental findings:

\_\_\_\_ Yes   \_\_\_\_ No

*[if applicable]* If you are providing permission on behalf of your child, your child will have the opportunity to change this decision once they turn the legal age of majority.

**Incidental Findings for Radiology Procedures:**

In some cases, an imaging scan of will reveal an abnormality with (or without) a clinical significance. Each scan done in this study is reviewed by a licensed radiologist, who might then detect an abnormality. If clinically useful information is uncovered, either the Principal Investigator or another clinician on the study will speak to you in person or on the telephone regarding the new information. The findings will also be included in your medical record, which means that anybody authorized to see your medical record (i.e. your treating doctor) will have access to these findings.

It is possible that you may have a condition or genetic predisposition that we do not come across as part of this research. If you would like a comprehensive review of your genetic information, we recommend that you undergo further validated genetic testing and seek genetic counseling.

***[Communicating with the Research Team via Text Message:*** *Include the following statement if protocol permits you to contact subjects via text message for study related communications]*

In this study you may receive texting over mobile/cell phones and this method of communication may result in a breach of your confidential information because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

1. What are the possible benefits of the study?

You *[may not/will not]* benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because *[describe why others might benefit in the future in terms of the knowledge that will be gained].*

*[Compensation/extra credit is not a benefit and should not be listed as a benefit.]*

1. What other choices do I have if I do not participate?

*[Open this section with the following statement]*

You may choose to not participate in this research study.

*[and, if applicable, list any and all currently available alternative procedure(s).]*

*[If there is no alternative to participation, the opening statement is sufficient.]*

*[For studies awarding course credit for participation, describe the IRB-approved alternative(s) to research participation, for which equal credit will be awarded]*

If you do not wish to participate in this study, the following alternatives are available:

1. Will I be paid for being in this study?

You will be paid to take part in this study. We will pay you by *[method of payment].*

*[If payment is by check or ClinCard:]*

As is required by the laws that apply to NYU Langone Health, in order for you to receive a payment (i.e. check, ClinCard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W-9 form.  If you do not have either of these numbers or are not willing to complete the IRS W-9 form, you may be in the study but will not receive any payment.

If you do not have either of these numbers, you may be in the study but will not receive payment.

You will be paid per completed *[visit, procedure, etc.]* If you choose to leave or are withdrawn from the study for any reason before finishing the entire study*,* you will be paid for each completed *[visit, procedure, etc.]* You will receive payment within *[number of days, weeks]* after your last study visit.

If you complete all the study visits, you will receive *[$0.00]* for being in this study.

*Or*

You will not be paid for being in this study.

*[Insert if applicable:]*

We will pay you back for travel costs to and from the study site and any hotel costs related to the study. In order to be paid, you must have given the receipts to the study staff. You can expect to receive a refund check in about *[XXX]* weeks.

1. Will I have to pay for anything?

*[Choose one:]*

There will be no cost to you for being in this research study.

*Or*

There will be costs to you for being in this study.

*[May include:]*

You or your insurance will be billed for some study costs.

*[Either:]*

Your insurance may not pay for all of the costs that we bill them for. You are responsible for any costs that your insurance does not pay. These costs may include co-payments, deductibles, insurance denials and/or balances due because of limited insurance.

 *[And/or]*

This study involves procedures that are the *standard of care*. This means that these procedures are a usual part of treatment for *[name of condition]* and you would have been given these procedures even if you were not in the study. You or your insurance will be billed for these procedures.

 *[Name of Sponsor]* is providing financial support to *[NYU Langone Health or Name of Your Institution]* to conduct this study.

*[If applicable]* If you agree to receive the results of any incidental findings, this may require additional scans *[or]* validated genetic testing and genetic counseling. You or your insurance company will be responsible for any costs associated with following up on the finding.

1. What happens if I am injured from being in the study?
2. When is the study over? Can I leave the study before it ends?
3. How will you protect my confidentiality?

**What is an Electronic Medical Record?**

An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

**What may be placed in the EMR?**

Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.

This information will be accessible to other members of the NYU Langone Health workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

**Will I have access to research-related information within the Electronic Medical Record?**

*[Include in this section language if there will be no delays in sharing study information within the EMR]*

The 21st Century Cures Act allows patients increased access to their EMR. If you agree to participate in this study, this means that any research-related information placed in your EMR will be available to you immediately.

As a research participant, this means that you have immediate access to any research-related information that is placed in your EMR before the researchers have had an opportunity to review the information.

*[You have the 3 options regarding how EMR/EPIC information will be disseminated to subjects, chose the most applicable option)*

***OPTION 1*** *- Please utilize this section If you would like to discuss study information that will be placed in the medical record.]*

The research-related information that will be available to you immediately are as follows:

* Results that may be placed in the medical record: *[List results from testing conducted in a laboratory or center that is part of the NYU Langone Health (i.e., the results would have been placed in the medical record, regardless of research participation)].*

Access to research-related information within your EMR can be found through NYU Langone Health’s patient portal, MyChart.

*[Include in this section language when certain research-related information will not be immediately accessible to the subject.* ***If there will be no delays in sharing study information within the EMR, the paragraph below should not be included]***

The 21st Century Cures Act allows patients increased access to their EMR. However, the law allows for exceptions to your immediate access to certain research information when needed for the research study.

As a research participant in this study, some research-related information will be placed in your EMR and will be available to you immediately and some research-related information will not be available to you until the end of the study.

The research-related information that will be available to you immediately are as follows:

* ***Results in the medical record that will be immediately accessible:*** *[List results from testing conducted in a laboratory or center that is part of the NYU Langone Health (i.e., the results would have been placed in the medical record, regardless of research participation)].*

For these results, you will have access to the research-related information placed in your EMR before the researchers have had the opportunity to review the information.

***[OPTION 2 -*** *Use this section to discuss study information that will not be available until the end of the study.]*

In this study, some research-related information in your EMR will not be available to you until the end of the study. This information will not be accessible in your EMR immediately in order to protect the integrity of the research trial results or *[you can list other reasons here].*

* ***Results in the medical record that will not be immediately accessible:*** *[List results from testing conducted in a laboratory or center that is part of the NYU Langone Health (i.e., the results would have been placed in the medical record, regardless of research participation)].*

*[Add details about what will be shared with research participants immediately, in a delayed manner, shared at the end of the study, and/or not shared at all. For example: “test results will be shared with you in a delayed manner, but other study information (e.g., progress notes and research notes) will be withheld until the end of the study.”]*

The researchers will provide you access to this research-related information in your EMR when the study is over.

***[OPTION 3 -*** *Please utilize this section If you would like to discuss study information that* ***will never be made available in the EMR.]***

In this study, some research-related information will never be made available to you in your EMR. This information will not be accessible in your EMR because *[list reasons why not available: e.g. the information is specific to this research and is not part of your medical history and clinical care; the information is from a non-CLIA certified laboratory; etc.].*

* ***Results that will not be placed in the medical record: [****List Research-Related Information that will never be accessible in the EMR – such as results would not have been placed in the medical record as part of clinical care and results from biospecimen testing conducted in a laboratory that is not part of the NYU Langone Health covered entity OR results from testing conducted in a non-CLIA certified laboratory.]*

*[Use this section when your study is funded by the National Institutes of Health]*

**Certificate of Confidentiality**

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

*[If the study will store study-related information in EPIC use the language below inserted in Confidentiality section]*

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, X-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

*[If the study involves enrollment of NYU Langone Health students and/or employees, include the following as applicable]*

If you are a student or employee of NYU Langone Health, note that your research information may be accessible to supervisors or others not directly involved in the research as needed for your medical treatment.

*[If the study involves the collection of data from or about subjects in the European Union, include the paragraph below]*

**Collection of Data from or about Subjects in the European Union**

The researchers will collect and use personally identifiable information in the course of conducting this research. This means that if you agree to take part in this research study, the researchers will collect data about you in the ways needed in order to conduct the study.

As indicated, the Principal Investigator of this study is *[insert Principal Investigator’s (PI) name], [insert PI’s NYU Langone Health department]*, at the NYU Langone Health and the Principal Investigator are jointly responsible for the conduct of this research study. NYU Langone Health will act as the data controller for this study and is responsible for looking after your information and using it properly. NYU Langone Health will keep identifiable information about you *[for x years after the study has finished / until x].*

You have certain rights with respect to the identifiable information collected about you during this study. These rights include:

* The right to request access to the personally identifiable information that the researchers have collected about you, as well as the right to request rectification of any information that is inaccurate or incomplete.
* The right to request a copy of your personally identifiable information in electronic format so that you can transmit the data to third parties, or to request that the researchers directly transfer your personally identifiable information to one or more third parties.
* The right to object to the use of your personally identifiable information for one or more purposes, including if you withdraw from this study, to object to the continued use of this information for the purposes of the research.
* The right to erasure of your personally identifiable information when it is no longer needed for the purposes for which you provided it, as well as the right to restriction of processing of your personally identifiable information to certain limited purposes where erasure is not possible.

If you agree to participate in this study but later change your mind, the researchers will keep the information about you that they have already obtained, unless you request otherwise. After you have agreed to participate in this study, your rights to access, change, move, erase, or object to the continued use of information already collected about you may be limited, as the researchers need to manage your information in specific ways in order for the research to be reliable and accurate. To safeguard your rights, the researchers will use the minimum personally identifiable information possible.

The researchers’ legal basis for the collection and use of personally identifiable information about you is their legitimate interests in the collection of reliable and accurate data for scientific analysis.

To exercise any of the above rights, you should contact the Principal Investigator at the contact information provided *[choose above or below].* If you have any concerns or complaints with respect to the handling of your personally identifiable information in this study, you can contact New York University’s Data Protection Officer, Peter Christensen, by phone: +1 212-992-7256, e-mail: peter.christensen@nyu.edu, or mailing: 70 Washington Square South, Room 1201, New York, NY, 10012. If you are not satisfied with the Data Protection Officer’s response or if you believe that the researchers are using your personally identifiable information in a way that is not lawful, you can complain to the following data protection authority: *[insert Data Protection Authority contact information*].

*[If the study involves the collection of sensitive data from or about subjects in the European Union, include the paragraph below]*

**Collection of Sensitive Data from or about Subjects in the European Union:**

This research study involves the collection and analysis of *[choose i,ii, or iii: (i) information revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership; (ii) genetic or biometric data, or (iii) data concerning health, sex life, or sexual orientation].* Your explicit consent is required for the collection of this information. By agreeing to participate in this study, you are consenting to the collection of this information.

*[If the study involves the transfer of data from or about subjects in the European Union to other jurisdictions, include the paragraph below]*

**Transfer of Data From or about Subjects in the European Union to Other Jurisdictions**

NYU Langone Health is a global medical center, research institution, and NYU Grossman School of Medicine, headquartered in the United States. If you agree to participate in this study, your personally identifiable information will be transmitted directly to NYU Langone Health researchers in the United States. Data protection laws in the United States may not be as stringent as the laws where you reside. By agreeing to participate in this study, you are consenting to the transmission of your personally identifiable information to NYU Langone Health researchers in the United States.

*[If the study is commercially sponsored clinical research, include the paragraph below]*

The Principal Investigator, researchers, and others who may be involved in your healthcare will use your personally identifiable information, as needed, to contact you about the research study, make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. The Principal Investigator will replace your name and contact details with a study identification code before reporting information about your participation in the study to *[insert sponsor organization].* Certain individuals from *[insert sponsor organization]* and regulatory organizations may look at your medical and research records to check the accuracy of the research study. The only people in *[insert sponsor organization]* who will have access to information that identifies you will be people who need to monitor study procedures or audit the data collection process. The people who analyze the information will not have access to your name or contact details.

**AND**

*[insert company name],* as the sponsor of this study, and NYU Langone Health are joint controllers of the personally identifiable information collected. *[insert company name]*’s Data Protection Officer is *[insert name]* and *[choose he or she]* can be contacted at *[insert contact information*]. *[Insert further information concerning the sponsor’s processing of the personally identifiable information, any recipients of the information, etc.]*

**OR**

NYU Langone Health will act as the data controller of personally identifiable information used to deliver medical care during the study. *[insert company name],* as the sponsor of the study, will be the controller of the coded information reported by the Principal Investigator. *[insert company name]*’s Data Protection Officer is [insert name] and *[ choose he or she]* can be contacted at *[insert contact information]. [Insert further information concerning the sponsor’s processing of the coded information, any recipients of the information, etc.]*

1. HIPAA Authorization
2. The Institutional Review Board (IRB) and how it protects you
3. Who can I call with questions, or if I’m concerned about my rights as a research subject?
4. Research with Applications, Software & Novel Technology

 [Please consult the Institutional Review Boards’ Guidance on Research with Digital Data Collection Tools, available in the IRB Template Library. Contact MCIT in advance if you intend to use novel technology, applications, or software as indicated in the guidance]

[Choose language as applicable to the mobile application, wearable device and/or software being used in this study.]

This study will use a [CHOOSE AS APPLICABLE: mobile application/and wearable device/software] to gather information for the researchers as part of this study. This [CHOOSE AS APPLICABLE: mobile application/and wearable device/software] is provided by [INSERT VENDOR NAME] and there are terms of use that the vendor requires of all users. You will need to review the vendor’s terms of use and privacy policy. The vendor may retain some of the data collected through the [CHOOSE AS APPLICABLE: mobile application/and wearable device/software], even after the study ends. If you do not want this data collection to continue by the vendor after the study ends, you will need to uninstall/discontinue use of [CHOOSE AS APPLICABLE: mobile application/and wearable device/software]. Even after you have uninstalled the application, the vendor may still retain your data so make sure to read the privacy policy and EUA/TOS. The research team can help explain how to do this.

We will ask you to share information with us about your health and how active you are by using a product or device made by a company or organization. Products or devices are things like fitness trackers, mobile apps that can be used on a smartphone or tablet, websites and web apps, or types of computer software.

Add if applicable:

This mobile app is provided by [INSERT VENDOR NAME]. This application can collect information from your mobile phone that would identify your geographic location when data is collected. To help protect your privacy, the research team can help to deactivate the location services if you wish.

This [CHOOSE AS APPLICABLE: mobile application/and wearable device/software] will use the data function on your phone, and, depending on much data you use for other things, you may have data charges.

If you do not already have the product or device, we may give one to you to use for the study. If we give you a product or device to use, you must agree to the company’s rules before you can use it, just as if you bought the product or service for yourself. The researchers of the study do not control these rules. We will help you understand these rules in the “Terms of Service” or the “End User License Agreement” that come with the product or device. Please read these rules carefully. These rules may ask you to agree to certain things, like not to sue the company if something goes wrong with the product or device. These rules may also allow the company to get, keep, or give others a copy of your information that comes from the product or device. Although this study will protect the copy of your information that you give us, we cannot protect or control what the company does with the copy that goes to them. If you do not agree to the company’s rules, you do not have to take the product or device. You can say no and still be in other parts of the study.

[Add link to vendor privacy policy]