

**Example standardized language elements:**

**Biomedical Research Consent Form**

***THIS DOCUMENT****: is a companion document to the 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 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 Biomedical Research for required language. To download a copy of the Consent Form Template for developing a biomedical consent form, use this link:* [***Research Protocol Development & Guidance Tools***](http://irb.med.nyu.edu/researchers/library/templates)*.*

***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 past 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 Legal Counsel and the Office of Compliance, Integrity, and Internal Audit.*

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.

*[****Minors:*** *For studies enrolling subjects who are under 18]*

Some of the people who may be able to take part in this study may not be able to give consent because they are under 18 years of age (a minor). Instead, we will ask their parent(s) or legal guardian to give consent. We will also ask the minor to agree (give their assent) to take part in the study. They will be given an Assent Form to sign. Throughout the consent form, “you” always refers to the “subject” or person who takes part in the study.  
  
*[****Employees/Students:*** *For studies enrolling NYU Employees or NYU Students]*

*[****NYU Employee****]*

Your employment will not be affected by your decision to participate in this study.

*[****NYU Students****]*

Your academic status or grades will not be affected by your decision to participate in this study. Record of the participation cannot be linked to an academic record.

*[****NYU Employee and Students****]*

Your academic status or grades, or employment will not be affected by your decision to participate in this study. Record of the participation cannot be linked to an academic record.

1. What is the purpose of this 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. Medical condition is brief description of the medical condition being studied.

*[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 placebo study design]*

This research study will compare *[name of study drug]* to a placebo. The placebo looks just like *[name of study drug]*, but contains no medicine. During this study, you may get the placebo instead of *[name of study drug]*. A placebo is used in research studies to compare the results and side effects of the drug being studied to the results and side effects of taking no medication. This allows us to see if the drug being studied works and what side effects it causes.

*[For cross-over study design]*

At some time during the study, you will get the *[name of study drug]*. At another time, you will get [*name of study drug]*. This is to compare your reaction to the drug being studied with your reaction to *[name of study drug]*

*[For double blind study design]*

This study is called “double blind” because neither you nor the study staff knows if you are taking *[name of study drug]* or the placebo. The sponsor keeps records of which study drug you are taking. The study staff can get this information if needed.

*[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 either the study drug or the placebo. There are no special requirements or criteria to be in either group. You will have an *[explain to subject their chances of receiving study drug]* of receiving *[name of study drug]*.

*[For comparison study design]*

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

*[For equivalence study design]*

*[Name of FDA approved drug]* is already approved by the FDA for the treatment of *[medical condition being studied]*. The drug being studied, *[name of study drug]*, might be safer and more effective, it might be the same or it might not work as well. We do not know which drug is better or even if the drug(s) are the same. The purpose of this study is to help us find *[explanation of study aim]*

*[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 visit]*.

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 School of Medicine 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 NYULMC* ***(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 IF NYU Langone Medical Center 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.]**

*[Pick appropriate phrase that best describes your study]*

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 some of the study will happen while you are in the hospital. Other study visits will be at *[location]* as an out-patient.

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

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. 7.5*

**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 ECG (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, marijuana, amphetamines and others. 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.*

**Visit 2: Your Baseline Visit**

This visit will take about *[describe time interval]*.

At this visit, we will:

Ask you about any medications you are taking and tell you if you need to stop taking any or all of them.

* + We may need to ask you to stop taking your *[name applicable concurrent medications and the length of time the subject should hold on taking them].*
  + This “washout period” allows your regular medication(s) to leave your body before you begin taking the study drug.
  + Without your regular medication(s), your *[medical condition/disease]* may get worse. If this happens, please call the study doctor right away at number listed at the top of page 1 of this Consent Form.

Remind you that you need to tell the study staff if you start taking any other medications during the study. The study staff will ask you about your medications at each study visit.

**Study Drug Instructions**

*Include study drug instructions, timing of dosing, if taken before or with meals. Include any specific study instructions regarding other drugs or foods that can/cannot be taken while on the study drug, or how much fluids to be given with study drug. Include any restrictions or precautions regarding alcohol intake and driving/operating heavy machinery, etc. If the first dose of the study drug will be taken during a visit, explain how long the subject will remain for observation afterwards.*

You will take *[name of study drug]* for the entire study. *[Explain detail, how taken, time of day to be taken]*. It is important that you follow the instructions you are given about how to take name of study drug/formulation/device/procedure.

The study staff will need to check your study drug so bring all of the bottles you have been given to each visit. DO NOT throw away empty bottles when you finish the medicine. Bring empty bottles and bottles that still have medicine in them when you come to each visit.

*[****Self dosing****: Include statement in studies requiring self-dosing]*

You must keep *[name of study drug]* where children cannot reach it.

*[****Study drug diary****: Include statement if you are asking subject to keep a study diary.]*

**Your Study Drug Diary**

We will give you a study drug diary to fill out at home each day. You will write in the diary to record the time you took the study drug, and if there were any changes in your overall health. Bring this diary with you to each 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 all together. 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.

*[****HIV Testing:*** *Include the following for studies with HIV testing]*

**HIV Testing**

You are being asked to consent to HIV testing for the purposes of this research. These tests might involve collecting and testing blood, urine or oral fluid. The most common test for HIV is the anti-body test, which is a blood test.

*[Include an explanation regarding why the HIV testing is a necessary component of this research i.e. HIV testing is a mandatory pre-screening requirement for research participation].* A positive test result means that you have been exposed to the virus and are infected. It does not mean that you have AIDS or that you will become sick with AIDS in the future. A negative test means that you are probably not infected with the virus. It takes the body time to produce HIV antibodies. If you have been exposed to HIV recently, you need to be retested in several months to make sure you are not infected. Your doctor or counselor will explain this to you.

If you permit the HIV testing and the results show that you have HIV, you will be told this in confidence by your study doctor and be given information about medical follow-up and will talk with you about telling your sex or needle-sharing partners of possible exposure. Additional testing may occur on the sample you provide to determine the best treatment for you and to help guide HIV prevention programs. You may (or may not) be allowed to participate in this study. Positive results for HIV will be reported to the local health authorities in your country, if required by law.

Your signature below indicates that your health care provider has answered any questions you have about HIV/AIDS and you have been provided information with the following details about HIV testing:

* HIV is the virus that causes AIDS and can be transmitted through unprotected sex (vaginal, anal, or oral sex) with someone who has HIV; contact with blood as in sharing needles (piercing, tattooing, drug equipment including needles), by HIV-infected pregnant women to their infants during pregnancy or delivery, or while breast feeding.
* There are treatments for HIV/AIDS that can help an individual stay healthy.
* Individuals with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from becoming infected or being infected themselves with different strains of HIV.
* The law protects the confidentiality of HIV test results and other related information.
* The law prohibits discrimination based on an individual’s HIV status and services are available to help with such consequences.
* The law allows an individual’s informed consent for HIV related testing to be valid for such testing until such consent is revoked by the subject of the HIV test or expires by its terms.

You may revoke your consent orally or in writing at any time. As long as this consent is in force, your provider may conduct additional tests without asking you to sign another consent form. In those cases, your provider will tell you if other HIV tests will be performed and will note this in your medical record.

Under New York State law, HIV-related information can only be disclosed to people authorized by you by signing a written release. Because the HIV test is needed to conduct this research, it is also necessary to obtain your authorization to share the HIV-related health information with those individuals who are conducting or overseeing the research. Those individuals who may receive your HIV-related information are listed in the “*[Who can see or use my information].* Your signature on this informed consent is your authorization that your HIV-related health information can be released to those individuals. This authorization shall be valid for the same period of time that you have authorized release of your other protected health information for this study, and likewise can be revoked at any time.

Under New York State law, HIV-related health information may also be released to the following: health providers caring for you or your exposed child; health officials when required by law; insurers to permit payment; persons involved in foster care or adoption; official correctional, probation and parole staff; emergency or health care staff who are accidentally exposed to your blood; or by special court order.

Under New York State law, anyone who illegally discloses HIV-related information may be punished by a fine of up to $5,000 and a jail term of up to one year. However, some re-disclosures of health and/or HIV- related information are not protected under federal law. For more information about HIV confidentiality, call the New York State Department of Health HIV Confidentiality Hotline at 1-800-962-5065; for more information regarding federal privacy protection, call the Office for Civil Rights at 1-800-368-1019. You may also contact the NYS Division of Human Rights at 1-888-392-3644.

1. What are the possible risks or discomforts?

**Risk of Study Drug**

Taking *[name of study drug]* may cause you to have one or more of the side effects listed below. The FDA considers the use *[name of study drug]* to be investigational for treating *[insert name of condition/disease]*. Because this is a research study about *[name of study drug]*, not all side effects are known. There may be rare and unknown side effects. Some of these side effects may be bad enough to cause death.

It is important for you to tell the study staff and study doctor about any changes you feel after you begin taking the study drug. You can tell the study staff at your scheduled visits or by calling the staff and telling them how you might feel different. If you are not honest with the study staff during this study, it may not be safe for you to stay in the study.

Below is a list of the most common side effect of *[name of study drug]*

Below is a list of less common side effects of *[name of study drug]*:

Below is a list of rare side effects of *[name of study drug]*:

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away at the phone number at the top of page 1 of this consent form. If you are having trouble breathing, call 911 immediately.

*[name of study drug]*can cause drowsiness, dizziness and blurred vision *[alter/delete as appropriate]*. You should be careful with heights (including stairs), driving a car and working with machinery until you see if you get these side effects and how bad these side effects are.

Your body forms antibodies when there is something unusual in your blood. This may include medications. An antibody is a type of protein that helps protect the body from bacteria and viruses. You may form antibodies because of the name of study drug. There is a small chance that if you have these antibodies, this drug or similar drugs will not work for you in the future.

In addition to the side effects listed above, you may experience physical, emotional, financial, social and legal risks and discomforts.

**NOTE**: If the research involves a placebo, there is a chance you will not actually be taking medicine that will treat your condition. In this case, your condition might not improve or could get worse. You could miss the benefits or harms (if any) of the study medication.

**Risk of taking other medication with study drug**

DO NOT take the following medications while you are in this study:

*[name of contraindicated medications – listed in bullet points (If this list would be too long, insert and provide IRB with Drugs to be Avoided list)]*

Taking these medicines and the study drug together may cause serious side effects. Your study doctor and study staff will tell you what other drugs you should not be taking while on the study drug. The study staff will give you a list of the medications you cannot take.

For your safety during the study, call your study doctor BEFORE you take:

New medications prescribed by any other doctor

Any medications sold over-the-counter without a prescription (including Tylenol, aspirin, cold medicine)

Dietary, vitamin or herbal supplements

**NOTE**: When you take more than one medicine at a time, the side effects can be worse or different than if you take either medicine by itself.

**Other Risks**

*[Include a description of any reasonable foreseeable risks or discomforts to the subject other than side effects of the study drug/procedures or procedures.]*

*[Subject confinement: [Below is required wording for confinement of two or more weeks.]*

The amount of time you have to spend in the research unit may make you uncomfortable.

*[As applicable, include any of the following sections:]*

**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.

**Xray Risks - standard**

During this study, you will have exposure to radiation from [*type of procedure can be specified or state - x-rays and other imaging tests*]. This radiation exposure is not necessary for your medical care and is for research purposes only. This means that you will be exposed to small doses or amounts of radiation. The risk from this amount of radiation is less than the risk from everyday exposure to the sun. The risks of receiving very small doses of radiation are thought to be low. These risks are not actually known.

Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an X-ray.

***If the Effective Dose will be from  3 to 50 mSv USE THIS LANGUAGE:***

*During this study, you will have exposure to radiation from [type of procedure can be specified or state - x-rays and other imaging tests]. This radiation exposure is not necessary for your medical care and is for research purposes only.  The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately [insert amount] mSv, which is equivalent to [insert amount (times or percent of)] the yearly natural background of radiation in the US (3 mSv).  The use of radiation may involve a low risk of cancer and is required to obtain the desired research information.*

Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an X-ray *[or insert other imaging test if applicable]*.

***If the Effective Dose will be from >50 mSv Use this Language:***

*During this study, you will have exposure to radiation from [type of procedure can be specified or state - x-rays and other imaging tests]. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be a maximum of approximately [insert amount] mSv, which is equivalent to [insert amount (times or percent of)] the yearly natural background of radiation in the US (3 mSv).  The use of radiation in this research study involves a low risk of cancer.  However, the NYULMC Radiation Safety Committee has reviewed the use of radiation in this research study and has found the use acceptable in relation to the potential benefits provided by the results of the study.*

Pregnant women cannot be exposed to radiation. Women must have a negative pregnancy test before they can have an X-ray *[or insert other imaging test if applicable]*.

**Electrocardiogram (ECG)**

The ECG test is a recording of the electrical activity of your heart and an ECG 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 Field Risk:**

MRI uses strong magnetic fields and radiowaves 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 radiowaves 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.

**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.

ADDITIONAL LANGUAGE:

**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. 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. 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.

1. Can I be in the study if I am pregnant or breastfeeding?
2. What if new information becomes available?
3. What are the possible benefits of the study?
4. What other choices do I have if I do not participate?

You do not have to take part in this research study to be treated for *[medical condition/disease]*. If you decide not to participate, your decision will not interfere with your future care, payment for your health care or your eligibility for health care benefits. Other treatments or procedures that are available to treat *[medical condition/disease]* include:

*[Insert appropriate alternative treatments and procedures using bullets; mention 3 – 5 alternative FDA-approved drugs/devices by name if applicable. Include palliative care or no other available treatment, when appropriate.]*

1. Will I be paid for being in this study?
2. Will I have to pay for anything?
3. What happens if I am injured from being in the study?
4. When the study is over? Can I leave the study before it ends?
5. How will you protect my confidentiality?

**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.

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 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 NYUSOM department]*, at the New York University School of Medicine (“NYUSOM”). NYUSOM and the Principal Investigator are jointly responsible for the conduct of this research study. NYUSOM will act as the data controller for this study and is responsible for looking after your information and using it properly. NYUSOM 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**

NYUSOM is a global medical center, research institution, and the Medical School of New York University, headquartered in the United States. If you agree to participate in this study, your personally identifiable information will be transmitted directly to NYUSOM 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 NYUSOM 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 NYUSOM 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**

NYUSOM 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