**Research Subject**

**Informed Consent Form (Specimen Banking)**

*This template can be used as a stand-alone informed consent for specimen banking, as an addendum to a main study informed consent document, or sections of it can be used in the body if the main study informed consent document.*

|  |  |
| --- | --- |
| **Title of Study:** | Insert Title of Research StudyInset Study Number |
| **Principal Investigator:** | Name of the Principal InvestigatorDepartment of Principal InvestigatorApplicable NYU School or CollegeAddressPhone Numbers |
| **Emergency Contact:** | Insert Emergency Contact Insert Phone Number/Pager, etc. |

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

***[NOTE TO RESEARCHERS****:]*

* *Reference is made to NYU Langone Health. For NYU (WSQ) researchers outside of NYU Langone Health, make sure you replace NYU Langone Health text with the applicable NYU School or College and change the NYU logo above as appropriate.*
* *All text in italics must be deleted from this document before submitting to the IRB.*
1. What is the purpose of this study?

The purpose of this research tissue bank is to collect, process, and store samples until researchers need them to do research. Tissue samples in this bank will be used mainly for research on *[state scope of research, e.g., breast cancer, cancer, cystic fibrosis]*. Research tissue banks collect and store many types of samples, such as blood, urine or other bodily material.

Our research tissue bank is located at *[specify location by institution/city].* There is no set limit to the number of individuals who provide samples to this bank. The more samples and health information we can collect, the more useful the tissue bank will be for research.

 *[Insert the name of the Sponsor/Funding Agency/Foundation, if applicable] is paying to have your samples processed and stored in this tissue bank”.*

**For what type of research will my samples be used?**

Your samples and information will be used mainly to *[describe the purpose of this collection and type of research which will be performed]*. The long-term goals of the research are to learn how to better understand, prevent, diagnose or treat *[insert condition].* It is not possible to list every research project. Also, we cannot predict all of the researchquestions that will be important over the next years. As we learn more, there are new research questions and new types of research related to *[insert condition]* may be done.

*Delete the following sentence if the tissue will only be used for the condition under study and related research*

Your samples and information may also be used for research on other conditions; for example, as comparisons to other diseases. This could include a wide variety of conditions such as mental illness, HIV/AIDS, cancer, and others.

***NOTE: If you want to restrict use of the samples only to the condition under study and research related to that condition, you may, but those restrictions should be stated in this section of the consent form and in the section entitled “What is the purpose of this research tissue bank?” and language permitting unrelated research should be deleted from those sections.***

**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**, aswell. 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?

Your participation in this study will last only for as long as it takes to draw your blood *[and if any other procedures add them here]*. This should take about *[insert # of days, months, years]* and will involve about *[# of visits]*.

About *[include total (all sites) study subjects]* between the ages of *[insert age range]* will be in this study.

*If multicenter, state that fact, list the number of centers and the approximate total number of participants that will be participating here. Otherwise, delete this line.*

This research study is happening at *NUMBER* other institutions as well.

*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 *[insert 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 *[insert location].* as an outpatient.

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

*For information that addresses the collection and storage of leftover materials after a clinically indicated procedure. Modify this section to accommodate the collection of dedicated samples exclusively for research; for example, drawing a blood sample or taking a skin biopsy solely for research. Customize or revise this section as needed for your tissue bank.*

*Include the following information in this section, when applicable:*

*• Description of study visits and procedures the research participants will undergo*

*• Description of any surveys/questionnaires that will be administered*

*• Expected time commitment for the visit(s)*

*If you are obtaining samples from your own patients during the performance of a clinically indicated procedure, state that the treatment decision has been made independent of this research tissue-banking project. State explicitly that the procedures/excisions are being done as part of routine medical care and would be done whether or not they give their permission for their samples to be stored in the tissue bank. If “extra” material will be taken for research, state this, and include the amount of extra material and, when applicable, any increase in procedure time.*

As part of your routine care, your doctor will obtain *[specify samples to be collected, e.g., tumor, blood, urine etc, and name all that are applicable.]* from you for testing. After the tests for your medical care are completed, part of your samples may be left over. Normally these leftover samples would be thrown away. We are asking you to allow us to collect and store this leftover *[specify samples to be collected e.g., tumor, blood, urine etc, name all that are applicable]* in a research tissue bank.

If you agree, the leftover samples will be frozen and sent to the bank. We are also asking for your permission to store some of your health information with your samples so that your samples **will be** more useful for research. We plan to continue to review your medical record to update your health information in the tissue bank computer database.

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

We will clean the skin over a vein in your arm. Then we will put a needle into the vein and draw blood into a tube. About *[provide volume in cc and household measure: 5 cc = 1tsp; 15 cc = 1 tbsp; 200 cc = 6 oz or ¾ cup]* of blood will be drawn.

We will collect some information from you or from your medical record. We want to understand how your blood sample tests relate to your other health information.

You will take part in this study only for as long as it takes to draw your blood. This should take about *[add how much time it will take]*. *[Include the next sentence, if relevant:]* We may ask you to return up to 3 more times to provide the same or a smaller amount of blood.

We will ask you a few questions about your medical history and take your temperature and pulse (heart rate). Then we will take a small amount of blood by finger stick or by vein (needle stick). We will check this blood sample to make sure that your blood cell counts are normal.

If the results of these tests are normal, we will clean the skin over a vein in your arm. Then we will put a needle into the vein and draw blood into a tube. We will draw up to *[insert the amount: i.e.550cc (about 2 cups, or one pint)]* of blood. This is the same amount of blood taken when you give blood at a blood bank. You should wait at least *[insert the number of weeks]* weeks before you give blood or have blood drawn for another research study. We will make sure you are feeling well after your blood is drawn.

1. What are the possible risks or discomforts?

**Risk of Study**

The main risk of allowing us to store and use your samples and certain limited health information for research is a potential loss of privacy. We will protect your privacy by labeling your samples and information only with a code, and keeping the key to the code in a password protected database.

Information that could be used to identify you will only be shared with researchers within NYU Langone Health who have approval of the IRB. Information that likely could be used to identify you will not be shared with researchers outside of NYU Langone Health.

*Include the non-medical risks of genetic testing, if applicable. The following language is suggested:*

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. To further safeguard your privacy, genetic information obtained in this study will not be placed in your medical record.

Taking part in a genetic study may also have a negative impact on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk.

Your doctor will explain the risks of the routine medical procedure you are having. In some cases, your doctor will ask you to sign a separate clinical consent form that explains the risks of the procedure. Allowing your samples to be placed in the bank will not change the risks of the medical procedure itself.

*If you will be taking or doing anything extra, e.g., blood draws, extra biopsy samples, the risks should be specified here.*

1. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

**Will I get results of research done using my samples?**

No. The research we are doing is only a stepping stone in understanding [condition]. Therefore, information from this research will not be returned to you or your doctor. Tests done for research using your samples will not be useful in directing your medical treatment. This information will not be placed in your medical records.

*If clinically useful information is expected, the answer to the question whether results of the research will be returned to the participant may be “yes” and this will require a different discussion (though the expectation is that results would be returned to the patient directly and not be placed in the medical record). Return of patient-specific research information to subjects must be extensively discussed in the protocol and consent form. If your group has a newsletter or other way of generally notifying subjects of research results; that could be mentioned here. For example, you may include the following sentence if applicable:*

However, you can choose to get a newsletter that will tell you about the research studies we are doing. This newsletter will not announce your results or anyone else’s, but it will tell you what we are learning about *[insert condition].* We will also publish what we learn in medical journals.

1. What are the possible benefits of the study?

You will not directly benefit from research conducted on your samples stored in the research tissue bank. We hope that research using the samples and information will help us understand, prevent, treat, or cure the illnesses and conditions studied.

**NOTE: 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 and, if applicable, list any and all currently available alternative procedure(s). If there is no alternative to participation, the opening statement is sufficient.*

You may choose to not participate in this research study.

*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:*

In order for you to receive a check, you need to give the study staff either your Social Security number or your Alien Registration number. If you do not have either of these numbers, you may be in the study but will not receive any 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?

*For studies where there are plans to charge certain costs to subjects and/or their health insurance:*

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

OR

*For studies where there are NO plans to charge certain costs to subjects and/or their health insurance:*

There is no cost to you to have your samples in the bank or for the research using your samples. The medical care you received that resulted in these leftover samples will be billed as usual to you and your health insurance company.

1. What happens if I am injured from being in the study?

*For research that poses greater than minimal risks to participants:*

*[ ]  Provide contact information for research-related injury (i.e. refer to the contact information noted in Consent header, if appropriate)*

*[ ]  Describe what treatment will be provided for research related injuries.*

*[ ]  Explain how treatment for research related injuries would be paid.*

*[ ]  Explain Subject’s responsibilities relating to research related injuries.*

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator’s name and phone number are listed at the top of page 1 of this consent form.

*Example language for non-industry-sponsored research. Modify for consistency with the clinical trial agreement.*

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

 *Example language for industry-sponsored research. Modify for consistency with the clinical trial agreement.*

We will offer you the care needed to treat injuries directly resulting from taking part in this research.  The study sponsor, *[insert name of study Sponsor]*, will pay the costs of the care you get as a direct result of your participation in the study.  If there are costs that the study sponsor does not pay for, we may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

***Note****: Insert this as last sentence after wording about payment for study-related injury:*

There are no plans for NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

*For NCI supported cancer trials, consider including the following information:*

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute’s website at: <http://cancer.gov/clinicaltrials/understanding/insurance-coverage>. Another way to get this information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

1. When is the study over? Can I leave the Study before it ends?

*[ ]  Define when the overall study is to end.*

*[ ]  Explain what events could lead to early study closure.*

*[ ]  Note that the subject can elect to leave the study at any time without penalty or loss of benefits to which the subject is otherwise entitled.*

*[ ]  If early withdrawal could expose the subject to medical risks, describe and how those risks will be minimized or prevented (e.g. in a hypertensive study, it may be necessary to wean a subject off the study medication or to transition them to alternate therapy).*

*Example for drug and device studies:*

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by your physician, the or study sponsor without your consent because:

* The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
* You have not followed study instructions.
* The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

1. How will my information be protected?

NYU Langone Health is committed to protecting the privacy and confidentiality of your health information. We are asking for your permission to use and to disclose your health information in connection with this study. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected.

**How are my samples stored?**

Staff at the bank will assign your sample a code number and store it in a freezer. They will not keep your name or other information that could identify you with your sample. They will use the code number to connect your sample to your health information that is stored in a computer database. The computer database is protected with a password. Only staff at the bank will know the password.

**What information about me may be used or shared with others?**

The following information may be used or shared in connection with this research:

*Edit the following as applicable: add or delete items as appropriate to your specific research protocol*

* Information in your medical record and research record, for example, results from your physical examinations, laboratory tests, procedures, questionnaires and diaries.

*Note: Genetic testing, HIV results, substance abuse treatment and mental health records may require different consents or language under applicable law.*

You have a right to access information in your medical record. In some cases when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

**Why is my information being used?**

Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

**Who may use and share information about me?**

The following individuals may use, share or receive your information for this research study:

* The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
* The study sponsor: *[specify name(s) of study sponsors. Delete this item if an NYU Langone Health department is the only study sponsor]*
* Governmental agencies responsible for research oversight (e.g., the U.S. Food and Drug Administration or FDA).
* Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
* Other study sites
* *Specify other non-NYU Langone Health persons/entities as applicable, for example:*
* *Contract research organizations*
* *Central research laboratories*
* *Study related committees/boards/centers (Data & Safety Monitoring Board, Endpoint Committees, Clinical or Data Coordination Centers, etc.)*

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

**Which researchers can use my samples and what information about me can they have?**

*Revise this section to reflect your plans for sharing of samples. Specify who will have access to samples in the tissue bank. Only your research group? Others at Partners? Outside academic and commercial collaborators?*

Your samples will be made available to researchers at NYU Langone Health and its affiliates. Occasionally, your samples may be shared with for-profit companies that are working with NYU Langone Health or other affiliate researchers on a specific research project. Your samples will not be sold to anyone for profit. The tissue bank will usually provide samples with limited information that does not directly identify you.

As described above, all of the samples stored in the bank are labeled with a code number that connects the sample to medical information related to the sample. The key to the code that links the samples and information to a specific individual will only be available to the tissue bank staff, and will be securely stored.

***OR***

Researchers at NYU Langone Health and the other institutions named above, whose studies have been approved by the NYU Langone Health Institutional Review Board (IRB), may be allowed to review your medical record to collect more health information about you. The IRB is a group that independently reviews and watches over all research studies involving people. The board follows state and federal laws and codes of ethics to make sure that the rights and welfare of people taking part in research studies are protected.

Researchers outside of NYU Langone Health and the other affiliates will not be given the key to the code that links your sample and medical information to your name or other direct identifiers.

***NOTE: The norm would be to allow all of these possibilities described in the paragraphs below. You can modify this section to be more specific or restrictive about access to samples, but then you must adhere to those restrictions. For example, you may wish to limit identifiable use to your research group and only allow others in the institution the use of coded samples without access to the key to the code. Or, you may not wish to include commercial collaborators. Please keep in mind that researchers outside Partners should never receive directly identifiable information or contact information.***

**How long will my samples and information be kept?**

There is no scheduled date on which your samples and information in the bank will be destroyed. Your samples may be stored for research until they are “used up.”

*If you requested establishment of cell lines, delete the second sentence and add the following sentence:*

Your sample will be used to create a living tissue sample, which may be stored and used for research indefinitely.

*If you did not request ongoing medical record review, the following sentence could be eliminated, but if you intend to review medical records going forward, leave this sentence in the consent form.*

The code linking your samples to your medical record may be kept indefinitely so that your samples and updated health information may be used for research in the future.

**Can I stop allowing my samples and information to be stored and used for research?**

*If samples are stripped of all identifiers and codes that link to identifiers, delete the following paragraph and simply state that the samples and data cannot be withdrawn.*

Yes. You have a right to withdraw your permission at any time. If you do, your samples and your information will be destroyed. However, it will not be possible to destroy samples and information that have already been given to researchers. If you decide to withdraw your permission, you should contact the tissue bank’s staff in writing *[provide name and contact information].*

1. Optional permission for future use

**Note**: The standard language scenarios for this section are already included in the Consent Form Template for non-biomedical research; to access that template click: (include the link to the Consent template).

 Or

**Will I be re-contacted for future research?**

*If you intend to re-contact the subject, include the statement below:*

We would also like your permission for the tissue bank staff to contact you in the future. This could be at a medical visit or by phone to get updated information about your medical condition or health status.

***Note: We recommend that you plan and describe all proposed research uses of tissues carefully “up front” rather than proposing to re-contact subjects to inquire about new uses or “re-consenting.” Re-contact is not prohibited, but if you expect to re-contact subjects, this must be stated in the consent form.***

*Insert this statement for specimens collected WITH personal health information (PHI):*

During the research, identifiable information about your health will be collected. In the reset of this section, we refer to this simply as “health information.” In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

* Past, present, and future medical records
* Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

* NYU Langone Health research staff involved in this study
* The sponsor(s) of this study, and the people or groups it hires to help perform this research
* Other researchers and medical centers that are part of this study and their ethics boards
* A group that oversees the data (study information) and safety of this research
* Non-research staff within NYU Langone Health who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
* NYU Langone Health Institutional Review Board that oversees the research and the NYU Langone Health research quality improvement programs.
* People from organizations that provide independent accreditation and oversight of hospitals and research
* People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
* Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
* Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
* Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside NYU Langone Health, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

*Insert this statement for specimens collected WITHOUT personal health information (PHI):*

Information about you collected for this research study will be stored in the investigator's research files and will be identified only by a number. Your name or other information that might identify you will not be recorded with or linked to your blood sample or your health information. This means that no one will be able to tell which specimen sample is yours. The research consent form you sign may be inspected and/or copied by the sponsoring agency, regulatory agencies or the NYU Langone Health Institutional Review Board in the course of carrying out their duties. If the signed research consent form is inspected or copied, the Hospitals will use reasonable efforts to protect your privacy.

1. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4140. The NYU Langone Health IRB is made up of:

* Doctors, nurses, non-scientists, and people from the Community
1. Who can I call with questions, or if I’m concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at 212-263-4140.

*Add this paragraph for studies requiring registration with ClinicalTrial.gov:*

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

|  |
| --- |
| **When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Subject (Print) |  | Signature of Subject |  | Date |
|  |  |  |  |  |
| Name of Person Obtaining Consent (Print) |  | Signature of Person Obtaining Consent |  | Date |

***[The following sections provide signature blocks necessary for other types of research including:***

* *Studies where it is necessary to use an authorized subject representative*
* *Pediatrics studies – for parental consent*
* *Studies using the short form consent process*
* *Studies involving subjects who cannot read*

*Select or delete a given section and its signature block as applicable for your specific study.]*

***[For studies using authorized subject representatives:***

*Use the authorization signature line only for studies that are approved by the IRB to permit subject representatives to authorize a subject’s participation in research. Delete if not applicable.]*

For subjects unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized subject representative:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Authorized Subject Representative (Print) |  | Signature of Person Obtaining Consent |  | Date |

Select the category that best describes the above Authorized Subject Representative:

[ ]  Court-appointed guardian

[ ]  Health care proxy

[ ]  Durable power of attorney

[ ]  Family member/next of kin; for this category describe relationship below:

***[For pediatric studies*** *(note: certain studies require the signature of both parents. If the IRB determines this is required, add another signature block for the other parent.)]*

**Signature of Parent(s)/Guardian for Child**

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Parent (Print) |  | Signature of Parent |  | Date |

***[For studies using the short form consent process:]***

**Witness to Consent of Non-English Speaking Subjects Using the “Short Form” in Subject’s Spoken Language**

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject’s own language, and that the subject was given the opportunity to ask questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Witness (Print) |  | Signature of Witness |  | Date |

***[For studies involving subjects who cannot read:]***

**Witness to Consent of a Subject Who Cannot Read or Write**

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject’s own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

[ ]  Subject making his/her own “X” above in the subject signature line

[ ]  Subject showed approval for participation in another way; describe:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of Witness (Print) |  | Signature of Witness |  | Date |