Research Participant
Informed Consent Form

Title of Study:	*Insert Title of Research Study* *Insert Study Number*
Principal Investigator:	*Name of the Principal Investigator* *Department of Principal Investigator* *Applicable Medical Center* *Address* *Phone Numbers*
Emergency Contact:	*Insert Emergency Contact* *Insert Phone Number/Pager, etc.*

About volunteering for this research study

You are being asked to join a research study, which will take place at **[insert institution name]**. This form tells important information about the research. A member of the research team will also speak with you about taking part in this study. People who take part in research studies are called "participants". This term will be used throughout the consent form.

You should ask questions of the person who is explaining this form to you. After you feel that you understand the research, if you want to be part of the study, you will be asked to sign the form. You can always ask more questions and can later change your mind about staying in the study. You will receive a copy of this form for your keeping.

You are a potential participant in this study because [insert reason the potential participant may qualify to be in the study]. Overall, this study will enroll **[insert number of subjects]** participants.

What is the purpose of this study and how much time will it take? *[For clinical trials/biomedical studies/cancer studies]*

Your participation in this research study will last *[Include participant's time in hours, days, weeks, months, years in appropriate terms for the objectives of the study]*

Phase I
The purpose of this research study is to test the safety of [study drug/intervention] at different dose levels. We would like to find out what effects, [good and/or bad], it has on you and your [specify disease. At the present time, this [drug/device] is [specify FDA status].

Phase II study
The purpose is to find out what effects, [good and/or bad], the [study drug/device/intervention] has on you and your [specify disease type. At the present time, this [drug/device] is [specify FDA status].

Phase III study
The purpose of this research study is to compare the effects, [good and/or bad], of [study drug/device/intervention] with [commonly used drug/ device/intervention] on you and your [specify disease type] to find out which is better. In this study, you will receive either the [study drug/device/intervention] or the [commonly used drug/device intervention]. You will not receive (or get) both. At the present time, this [drug/device] is [specify FDA status].

What will I be asked to do in the study?

If you take part in this study, you will have the following tests and procedures:

[List study procedures and their frequencies, differentiating between those that will be performed solely for research or investigational purposes, and those that represent standard of care.

For randomized studies, list the study groups and under each, describe procedures. Include whether a patient will be at home, in the hospital, or in an outpatient setting.

List the research medications that will be administered and the method, dose and frequency of administration. Indicate the number frequency and duration of visits.

For studies involving non-FDA approved drugs or devices indicate whether the participant will have access to them following the completion of the study. Indicate other specific requirements such as post-treatment follow-up, diary cards, and questionnaires.]

What are the possible risks or discomforts?

Participation in this study may involve some added risks or discomforts. These may include those from study procedures and/or side effects of medications that are part of this study. In addition to the risks listed below, there may be risks that have not appeared before. You must contact the study doctor if you are concerned about anything during the course of your participation.

The risks and/or discomforts include the following:

List only the risks and side effects related to the investigational aspects of the study and any standard of care procedures that are mandated for entry and during the course of the study. Any risks from standard medical care procedures that are not specially mandated should not be included.

> *Example 1: A participant who is undergoing joint replacement surgery for osteoarthritis and the surgeon wants to participate in a trial of a new post-operative analgesic. The risks of the general anesthesia or orthopedic surgery do not need to be included in the research consent form because they are part of the treatment consent.*
> *Example 2: A participant with COPD who becomes part of a trial of a drug eluting stents versus medical management all of the risks regarding the stent procedure would need to be included even though the procedure is standard of care.*

Risks of drugs:

[Insert study drug 1 name] may cause some, all or none of the side-effects listed below.

List only the risks and side effects related to the investigational aspects of the study and do not list side effects of supportive medications unless the medications are specifically mandated by the study. Whenever possible, drug side effect should be expressed as "frequent x%", "Occasional x%", and "Rare x%". As a guide, "frequent" can be viewed as occurring in >20% of participants; "occasional" as 2-20% of participants, and "rare" as <2% of participants. If more specific data is not available, use the largest percent.

[Insert study drug 2 name] may cause some, all or none of the side-effects listed below.

List only the risks and side effects related to the investigational aspects of the study and do not list side effects of supportive medications unless the medications are specifically mandated by the study. Whenever possible, drug side effect should be expressed as "frequent x%", "Occasional x%", and "Rare x%". As a guide, "frequent" can be viewed as occurring in >20% of participants; "occasional" as 2-20% of participants, and "rare" as <2% of participants. If more specific data is not available, use the largest percent.

[Insert Placebo if used in the study]: A placebo looks like an active drug but has no active medication in it. If you receive a placebo, you will not receive medication for your health problem. If your health problem becomes worse, your participation in the research may stop. If this happens, your study doctor can discuss alternative care with you.

Pregnancy Risks:

Females: If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you can become pregnant, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes: (1) surgical sterilization (such as hysterectomy or "tubes tied"), (2) approved hormonal contraceptives (such as birth control pills, patch or ring; Depo-Provera, Implanon), (3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or (4) an intrauterine device (IUD).

If you do become pregnant during this study, you must tell the researchers immediately.

Risk from Radiation during pregnancy (if needed) If the study will include exposure to radiation, please include the following:
Radiation exposure to a woman's reproductive organs may harm an embryo or fetus. Also, if radioactive materials are used for certain types of scans, harm may come to an embryo, fetus, or an infant who is breast feeding.

Males: Being in this research may damage your sperm, which could cause harm to a child that you may father while on this study. If you take part in this study and are sexually active, you must agree to use a medically-acceptable form of birth control.

Medically-acceptable forms of birth control include: (1) surgical sterilization (vasectomy), or, (2) a condom used with a spermicide (a substance that kills sperm).

Radiation Risks: *[If this study involves exposure to radiation, please include the following two paragraphs:]*

(1) During your participation in this research study, you will be exposed to radiation from scheduled x-rays and/or imaging scans. The total exposure resulting from these imaging studies is calculated to be approximately [fill in with appropriate amount of exposure] mSv. This amount is [more/less/equal—choose one] than you would receive from one year of natural exposure depending on the altitude of your local area but is approximately 1.6 mSv. Cumulative exposure from radiation may increase your risk of developing certain types of cancer in the future.

(2) The principal investigator for this research study has determined and verified that [all/most/some—choose one] of the x-rays and/or imaging scans prescribed for this study would typically be performed as part of the standard medical care required to adequately monitor your current illness. [Investigator may be specific here by listing the scans that are considered standard of care if applicable or deemed to be useful information for the research participant. In addition, non-radiation producing imaging alternatives would be included here if described in the Research Plan.] If you are especially concerned with radiation exposure, or you have had a lot of x-rays or imaging scans already, you should discuss this with the principal investigator for this study, Dr. [fill in with name of principal investigator], or your regular doctor.

Risks of Blood Drawing: [if needed]. Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely.

[If blood samples are collected as part of the participants' standard medical care] You will have the same amount of blood collected whether you receive standard medical care for your health problem or take part in this research.

[If blood samples are collected solely for the purpose of research] You will have [insert amount in lay terms] of blood collected because you are in this research study.

Loss of Confidentiality:

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

What if new information becomes available?

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

What are the possible benefits of the study?

Because of the nature of research, it is possible that you may receive no benefit at all and others may benefit in the future. If there is a placebo group, then it is unlikely you will have any benefit. It is also possible that participating in the research study may make your condition worse.

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

Taking part in this study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with [Insert appropriate entity (e.g., hospital, university)].

[Instruction to the PI: If this is a treatment protocol, you must choose from one of the two paragraphs below, as appropriate and modify or complete the paragraph you choose with the required information. You can omit these paragraphs if your research study does not involve a treatment protocol]

A) There are other procedures or treatments for your disease. If you join this study, you will not be able to get these procedures or treatments. If you want to receive these procedures or treatments, you should not join this study.
B) At the present time, the researchers do not know any other procedures or treatments for your disease.

OR

If you decide not to participate in this study, there may be other treatments available including medications already on the market. Your study doctor will be able to provide additional information to you about these treatments. All of these alternative medications can cause side effects or allergic reactions. Your study doctor will discuss the potential side effects, benefits and risks of alternative treatments with you before you decide to participate in this study or if you choose to withdraw.

Will I have to pay for anything?

There will be no costs to you for participating in this research study. Procedures and tests that are part of the research will not have any costs associated with them. However, if you receive tests and/procedures that would have been done as part of your healthcare, these procedures will be billed to your insurance carrier as standard of care.

While you participate in this study, you may have costs which include such things as transportation, child care, time from work, if you are employed that are not reimbursed.

- *List the additional tests/visits/procedures to be performed for research purposes only. Describe who will be responsible for paying the cost of research tests, procedures, visits, etc. that are not standard of care.*
- *Clearly explain what the likely costs will be for participation in this research study and who will be responsible for those costs e.g. "… billed to you and/or your insurance." Or "… paid by the sponsor.*
- *Describe specific items or procedures that may/may not be covered. Include clinic fees, transportation, and parking fees (if known).*

- *Address clearly who will be responsible for the payment of the costs of standard treatment in the research study, e.g., "These costs will be billed to you or your insurance carrier."*

[The following section is open for modification by participating sites:

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

*[Instruction to PI: Include any language that may be applicable depending on the sponsor of the study, e.g., If as part of participating in the study, you are injured by the study drug or study-related procedures done to you in accordance with the study protocol**, [insert sponsor name]** will pay for reasonable and necessary medical expenses to treat the injury. **, [insert sponsor name]** is not offering to compensate you for any other expenses, but you do not waive any legal rights you may have to seek compensation by signing this consent form.]*

The **[insert Medical Center]** does not plan to pay for medical care that you may have as a result of taking part in this study. However, you do not give up any rights you may have to seek compensation by signing this form.

OR

If you suffer a bodily injury as a direct result of the Study Drug or any procedures required by the Protocol, The Sponsor will pay for all reasonable and necessary medical and hospital costs required for the treatment that is not covered by your medical insurance, government program or other responsible third party, or is not part of the natural progression of the disease being studied, or that bodily injury is due not to your other pre-existing condition(s), or bodily injury is not caused by your failure to follow instructions of the study staff, or **[insert Medical Center]** negligence or willful misconduct, or the study staff's failure to follow the Study Protocol.

For questions about the study or in the event of a research-related injury, contact [insert name of the study investigator, Name at telephone number (also include after-hours number).*]*

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

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.
If you decide to withdraw your consent to participate in this study, you should notify (name of PD) at (telephone number). *Clearly outline the study withdrawal procedures (Suggestion: check your protocol)*.

If you withdraw from the study, or the study medication is stopped for any reason,

- *add anticipated consequences, if any, of discontinuing the study drug or device.*
- *Clearly state the protocol-specific termination procedures.*
- *Instruct participants that they must return all study-related supplies, including unused study drug.*

The Principal Investigator may also withdraw you from the study *and the study medication may be stopped [if applicable],* without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the [insert drug name(s)]. In some cases, the abrupt stopping of a drug can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

You may be taken out of the study if it is felt that staying in the study would be harmful to you, if you need treatment not allowed in the study, if you do not follow instructions, if you become pregnant or if the study is cancelled. If you are withdrawn from the study, the reason will be explained to you.

[The following section is open for modification by participating sites:

If I take part in this research study, how will you protect my privacy?

Your privacy is very important to us. The study doctors will make every effort to protect it.

This study has support from the National Institutes of Health (NIH) and your study information is protected by a Certificate of Confidentiality. This certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.
It does not protect information that we must report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help. Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information 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:

- The 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 who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The IRB that oversees the research and the 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 US 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 and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside this institution, we cannot control all the ways that others use or share it and 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.*]*

[The following section is open for modification by participating sites:

What are your Rights?

You have the right not to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.*]*

How does the Institutional Review Board (IRB) protect you?

The Institutional Review Board (IRB) reviews all human participant research before it can be implemented and then regularly as long as there is any research activity. The primary concern of the IRB is for the protection of human participants participating in research. For questions about your rights as a research participant, contact the [insert institution name] Institutional Review Board (IRB) Office at [insert phone number / e-mail address].

Who can I call with questions, or if I'm concerned about my rights as a research participant?

You can call the IRB with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want. [Insert name and academic degrees] is the person in charge of this research study. If you want to speak with someone not directly involved in this research study, please contact [insert name of contact or IRB]. You can call them at [insert contact information].

- You can talk to them about:
- Your rights as a research participant
- Your concerns about the research
- A complaint about the research Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web 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 Participant (Print)	Signature of Participant	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 participant representative*
- *Pediatrics studies – for parental consent*
- *Studies using the short form consent process*
- *Studies involving participants who cannot read*

Select or delete a given section and it's signature block as applicable for your specific study.]

[For studies using authorized participant representatives:
Use the authorization signature line only for studies that are approved by the IRB to permit participant representatives to authorize a participant's participation in research. Delete if not applicable.]

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

Name of Authorized Participant Representative (Print)	Signature of Authorized Participant Representative	Date

Select the category that best describes the above Authorized Participant 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

[The following section is open for modification by participating sites:

[Genetic Screening "Rider" for Consent Forms]

Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a *[Insert type of sample, e.g. blood, urine, etc.]* for genetic research. What we learn about you from this sample (will not be) or (may be) put in your health record. [*If applicable insert:* Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.]

A single [*blood sample of X teaspoons or tablespoons will be drawn from a vein in your arm using a needle; cheek swab sample will be obtained by (indicate method); urine sample will be obtained by (indicate method); extra biopsy tissue will be obtained by (indicate method); or other (indicate what) sample will be obtained by (indicate method*.] This will take about *X minutes/hour* of your time.

If applicable insert:

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint.

Otherwise insert all risks, inconveniences or discomforts associated with specific type of sample collection

[Insert if true, this may not be applicable for personalized medicine testing:] One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only (investigator's name and/or other's names) will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

[COMMERCIALIZATION LANGUAGE OPTION — INSERT THE FOLLOWING, IF APPLICABLE]:

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, [institution], and/or others. If this happens, there are no plans to provide money to you.

[INSERT THE FOLLOWING STATEMENT IF TRUE]:

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

[Insert if genetic portion is optional]

Giving samples for research is your free choice and you may be in the study even if you do not want your samples used or stored for gene research.

At any time, you may ask to have your sample destroyed. You should contact [PI name or study staff] at [insert address/phone number] to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. [Insert if applicable: You will not be paid for the use of your samples.]

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research in _____.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____ *]*