TEMPLATE ICF – This document is the framework for a complete consent form. Site-specific information and study-specific information (directly from sponsor template) should replace gray highlighted/bracketed text as appropriate.

* See the embedded comments for additional guidance.
* Be sure to keep the “Tracked Changes” feature ON.
* Delete instructions.

**INSTITUTION NAME**

**SUBJECT INFORMATION AND INFORMED CONSENT FORM**

**Protocol Title**:

**Protocol #**:

**Sponsor**:

**Principal Investigator**:

**Institution**:

**Address**:

**Telephone**:

**Key Information Statement**

The purpose of this \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (study / registry / test) is to test / evaluate / help \_\_\_\_\_\_\_\_\_\_\_. Study subjects will \_\_\_\_\_\_\_\_\_ (answer questionnaires / provide one blood sample / have one scan). There is/are ## study visit(s). Participation is completely voluntary. There is the risk of loss of confidentiality of your medical and personal information collected for this study.

**If you are interested in learning more about this study, please continue to read below, where you will find additional information related to this study such as the risks, benefits, procedures, alternatives, and contact information.**

**KEY INFORMATION ABOUT THIS RESEARCH STUDY**

You are being asked to be a subject in a research study because you have \_\_\_\_\_\_\_\_\_\_\_\_.

**The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.**

|  |  |
| --- | --- |
| Purpose | Examples:  This is a research study to evaluate the safety and effectiveness of the study drug/device NAME.  -----------  This is a research study to evaluate the effectiveness of the study drug compared to Standard of Care treatment. |
| Experimental/ Investigational | Examples:  Study drug/device NAME is experimental which means that it is being tested and is not approved by the United States Food and Drug Administration (FDA).  You will/may receive standard of care drug(s) in addition to the experimental drug.  Instead of the experimental drug, you will/may receive placebo (‘dummy drug’) which is used to compare results to the experimental drug.  -----------  You will not receive any experimental drugs or procedures as part of this study. |
| Voluntary Participation | Your decision to be in this study is voluntary. |
| Withdrawal | If you decide to be in this study and then change your mind, you can leave the study at any time without penalty. |
| Length of Participation | Examples:  Your participation is expected to last up to ## weeks / months / years.  During that time you will have about ## study visits. [Include number of visits if excessive # or length of visits is very long; otherwise, not needed in summary.]  -----------  The length of time you are in this study and number of study visits depends on your response to the study drug regimen. It may last up to ## months/years. |
| Procedures | Include ONLY major procedures, i.e. not ECG, blood draw, eDiary, optional tests.  The main procedures in the study include:      Examples:   * ---Study drug infusions/injections/tablets taken weekly/daily/once * ---Implant of study device * ---Imaging scans * ---Biopsies * ---Angiogram * ---Genetic testing   The study doctor will explain which procedures are being done for research, and which would be done as part of your standard care even if you don’t participate. |
| Risks  [Use if more than minimal risk] | Taking part in this research may expose you to risks (side effects). Not all risks of the study drug(s)/device are known at this time. There are risks from study procedures. Side effects may range from being mild to life-threatening and may go away with treatment or be permanent.  The common/main risks of the study drug(s)/device NAME include:      Examples:   * ---increased risk of infections * ---severe allergic reaction * ---damage to liver, kidney and other organs * ---breakage of the stent damaging nearby organs   The study doctor will explain the risks of this research to you before you decide about participation. |
| Risks  [Use if minimal or no physical risks] | There are not expected to be any physical risks to you as part of this study. |
| Benefit | Examples:  There is no guarantee that you will benefit as a result of your participation in this study, however the study results may help people in the future.  -----------  There is no benefit to you from taking part in this study |
| Alternative(s) to Study Participation  [For 'treatment' studies only; otherwise delete box] | There may be other options for treatment of your condition including creating a treatment plan with your doctor. |
| Costs | The study sponsor will pay for the cost of the study drug(s)/device and for procedures that are required only for the study. |
| Confidentiality | There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information. |

|  |
| --- |
| This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation. |

**INFORMED CONSENT FORM**

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

**DISCLOSURE OF FINANCIAL INTERESTS**

Sponsor Name, the sponsor of this study, is providing funds to Institution or private practice on a per subject basis for conducting this research study.

**PURPOSE OF THE STUDY**

The purpose of this study is to evaluate the safety and effectiveness of an experimental drug/device called \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. An experimental drug/device is one that is being tested and is not approved by the United States Food and Drug Administration (FDA).

**NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION**

About ## subjects are expected to participate in this study at ## research sites in the United States / worldwide.

Your participation in this study is expected to last ## months / years.

# STUDY PROCEDURES

[Copy & Paste the sponsor template Procedures UNTRACKED (with Tracked Changes OFF). Then set Tracked Changes ON and revise Procedures text as needed. Do not delete “Note to Sponsor” comment.]

Be sure to consider the following, as applicable. Delete this instruction box.

* Define “*randomized*” or “*randomly assigned.*” Examples: “*like the flip of a coin*” (if the chances are 50/50), “*like the roll of the dice*”, “*by chance”,* or “*picking chances from a hat*”.
* Include the chances of receiving study drug vs. placebo. Examples: “*Your chances of receiving study drug are 50/50.”* “*Your chances of receiving placebo are 1 in 4.”*
* Include the dosage of study drug being administered to the subject. Example: “*If you are randomized to receive drug XXX, you will receive one of the following doses: 3 mg/kg/day, 6mg/kg/day, or 12 mg/kg/day.*”
* Include route of study drug administration (by mouth, injection, intravenous infusion).
* Explain double blind. “*Neither you nor the study doctor will know which study drug you receive. In the event of an emergency your study doctor can find out which drug you are receiving*.”
* Define washout period. “*A period of time in which you will be asked not to take your current medication.*”
* Define open-label, placebo controlled, or evaluator blind in lay language.
* Include duration of individual visits and procedures including questionnaires. Examples: “*Visit one is expected to last about 1 hour.” “The questionnaires will take about 15 minutes to complete.”*
* If a drug, device, test, or procedure employed in the course of the research study is considered part of routine clinical practice or standard patient care, this should be noted. Conversely, if participation in the research project entails an extra procedure (e.g. spinal tap, endoscopy, EKG, etc.), this must also be noted. Example: “*The MRIs done during the study are part of your routine care except the MRI done at Visit 8, which is being done only because you are in this study.”*
* Note restrictions and lifestyle requirements, such as foods or medications that must be avoided, if the patient must be accompanied home, if the patient will not be able to perform everyday functions, etc.
* Any videotaping or photography must be noted.
* If subjects will undergo surgery or other procedures that require anesthesia (general or local), this should be noted.

Genetic Research: Your genes are in the cells in your body. Genes make you different from anyone else. Some genes are responsible for inherited traits like hair and eye color. Some genes affect the chances that a person will get a certain disease or how their body responds to drugs. This study is being done to help researchers understand why people may react differently to the study drug and how the body uses the study drug. No tests other than those described in this form will be performed on your sample without your permission. Your sample will be destroyed when it is no longer needed. To help protect your privacy, your sample will be identified by your subject number, not your name. Only the study doctor and other authorized persons will be able to link your subject number with your name. Neither you nor your study doctor will be given the results of the testing.

**SUBJECT RESPONSIBILITIES**

As a subject in this study, you will have certain responsibilities, including the following:

* Attend all study visits and, if needed, reschedule appointments as soon as possible
* Follow the instructions of the study team
* Take the study drug as directed
* Tell the study doctor all medications that you are taking and check with the study doctor before taking any new medicines (including prescription, over-the-counter, vitamins and herbal supplements)
* Tell the study staff any time you do not feel well or if you have any side effects

# RISKS AND DISCOMFORTS

[Copy & Paste sponsor template Risks UNTRACKED (with Tracked Changes OFF). Then set Tracked Changes ON and edit as applicable. Do not delete “Note to Sponsor” comment.]

**Genetic Research Risks**: The sponsor has taken steps to safeguard your genetic testing information, so the risk of loss of confidentiality is small, however, if confidentiality is broken, results of genetic testing may become available to insurance carriers or employers. The knowledge of this information has the potential to lead to discrimination in employment or insurance. Someone with a known genetic condition indicating a susceptibility to develop a disease or condition might be denied a job or a promotion, or denied health or life insurance, because they are regarded as a health risks and therefore an economic risk. Carriers for a genetic disorder might be discriminated against and viewed as having the potential to have a child with a genetic condition.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers (except those with fewer than 15 employees) to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**NEW INFORMATION**

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Clinically Relevant Research Results

The overall results of this study may or may not be available to you at the end of the study.

The study doctor will also explain if and when you will receive individual research results that may have clinical significance.

**BENEFITS**

There is no guarantee that your condition will improve as a result of your participation in this study. It may stay the same or worsen. However, the information learned from this study may help other people with this disease in the future. Even if the study drug helps you, it will not be available to you after the study is over.

**ALTERNATIVES TO STUDY PARTICIPATION**

You do not have to participate in this study to receive treatment for your condition. There are treatments such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You may also choose to have treatment for your symptoms only (palliative care) or to have no treatment. The study doctor will discuss study alternatives with you and their risks and benefits.

**COSTS OF PARTICIPATION**

The sponsor of this study will provide the study drug/device (insert name of drug and placebo, as applicable) to you at no charge. The sponsor also covers the cost of assessments and procedures required only for this study.

You and/or your insurance company will be responsible for the costs of all items and services during the research study, which you would have received for your condition if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you. You should discuss possible costs of study participation with the study staff and/or your insurance company.

**REIMBURSEMENT**

You will receive $## for each visit toward your study related expenses such as travel and parking. If you leave the study early, you will be reimbursed only for visits you complete. You will be reimbursed by ClinCard at the completion of each study visit.

Tax law may require the payer (e.g. research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

Your biospecimens, with or without identifiers, may be used for commercial profit and you will not share in this profit.

**COMPENSATION FOR INJURY**

For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your study doctor immediately. The study doctor will assist you in obtaining appropriate medical treatment.  The institution will not be responsible for the costs of treatment caused by the properly performed study procedures and/or study drug/device.

The sponsor will pay for reasonable and necessary medical treatment of injuries and illness that are a direct result of study procedures and/or study drug/device that are required by the study protocol and that were done correctly and only because you were in this study.

The sponsor will not cover the costs of your study-related injury or illness if:

* The sponsor and/or the study doctor do not think the condition or injury is a direct result of your being in the study;
* The injury is attributable to the underlying disease or a pre-existing medical condition or the natural progression of an underlying disease or was deliberately caused;
* You do not follow the instructions of the study plan;

No other compensation will be offered by the sponsor or [INSTITUTION] or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort.  You are not waiving any legal right to seek additional compensation through the courts by signing this form.

**CONFIDENTIALITY**

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor’s representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

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.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

* Past and present medical records
* Research records
* Records about phone calls made as part of this research
* Records about your study visits
* Information obtained during this research about laboratory test results
* Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
* Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

* The U.S. Food and Drug Administration
* Department of Health and Human Services agencies
* Governmental agencies in other countries
* Biomedical Research Alliance of New York (BRANY)
* The Institutional Review Board
* Accrediting agencies
* Data safety monitoring boards
* Health insurers and payers
* Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date.  Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Collection of Identifiable Private Information or Identifiable Biospecimens:

* Identifiers might be removed from your identifiable private information or identifiable biospecimens. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

OR

* Your information and biospecimens collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies responsible for protecting your rights.

**VOLUNTARY PARTICIPATION AND WITHDRAWAL**

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor’s office for a final study visit for your safety.

**CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS**

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. [Principal Investigator] at [PI Phone Number].

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at [www.branyirb.com/concerns-about-research](http://www.branyirb.com/concerns-about-research).

**STATEMENT OF CONSENT - SIGNATURES**

By signing this form, I confirm the following:

* I have read all of this consent form.
* All of my questions have been answered to my satisfaction.
* I can leave the study at any time without giving a reason and without penalty.
* I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
* I will be given a copy of this signed and dated consent form to keep.
* I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

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**Subject**: Name (Print) Signature Date

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**Person Obtaining Consent**: Name (Print) Signature Date

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**Legally Authorized Representative**: Name (Printed) Signature Date