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 GRAY instructions prior to submission to BRANY.



**NATIONAL JEWISH HEALTH**

**SUBJECT INFORMATION, INFORMED CONSENT, AND HIPAA AUTHORIZATION FORM**

**Protocol Title**:

**Protocol #**:

**Sponsor**:

**Principal Investigator**:

**Institution**: National Jewish Health / may add name of specific location

**Address**:

**Telephone**: ###-###-#### (Office hours) ###-###-#### (After hours messages)

For study greater than minimal risk, also include the following, else delete

###-###-#### (24 hour contact for urgent matters)

 In an emergency, dial 911

Include and customize this paragraph for studies enrolling adults who cannot consent for themselves, or for parents/legal guardians providing permission for minor subjects:

Legally Authorized Representative or Parent/Legal Guardian: Some of the people who may be able to take part in this study may not be able to give consent to participate because [of their medical condition/disability/they are under 18 years of age]. **If you are consenting for someone else to take part in this study, note that the words ‘you’ and ‘your’ in this form refer to the person (subject) taking part in the study, not to you.**

**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 | This is a Phase [1 / 2/ 3] research study being conducted 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 | 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 | Your participation is expected to last up to ## weeks / months / years. During that time you will have about ## study visits. [Include if excessive # or length of visits is very long]-----------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. There will be about XX number of subjects in this study at NJH. |
| Procedures | The main procedures in the study include:------ ---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 and delete Risks box below] | 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 include:------ ---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 and delete Risks box above] | 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 | There may be other options for treatment of your condition including creating a treatment plan with your doctor.For ‘non-treatment’ studies, registries, etc.:Your alternative is to not take part in this study. |
| 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.

The study doctor may be both your health care provider and the study doctor for this study. The study doctor is interested in both your clinical welfare and in the conduct of this study. Before entering this study, or at any time during the study, you may ask for a second opinion about your care from another clinician who is not associated in any way with this study.

**DISCLOSURE OF FINANCIAL INTERESTS (If applicable; You will be told specific language for this section per the conflict management plan)**

[Sponsor Name], the sponsor of this study, is providing funds to National Jewish Health on a per subject basis for conducting this research study. [Investigator’s Name], investigator(s) responsible for the conduct of this research study, have been compensated for consulting services by the sponsor during the past year.

**PURPOSE OF THE STUDY**

State the objectives/goals of the research project in lay terms. (May copy/paste from sponsor template)

e.g., The purpose of this study is to evaluate the safety and effectiveness of an experimental drug/device called \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

If applicable: 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**

About ## subjects are expected to participate in this study at NJH. (add the following if a multicenter study) A total of about ## subjects are expected to participate at ## research sites in the United States/ worldwide.

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

# STUDY PROCEDURES

**INSTRUCTIONS:** Be sure to include all research-related procedures, including every visit and procedure, e.g. blood draws\*, EKGs, injections, follow up phone calls, pulmonary function testing, pregnancy test, x-ray , questionnaires, diaries, use of Holter monitor.

See NJH Standard Statements document (on NJH HRPP website) to describe procedures and risks

* If blood is being drawn, include the amount of blood to be drawn. For example: *Approximately 7 tablespoons of blood will be drawn during the course of the study*. Use measurements familiar to subjects, e.g. teaspoons, tablespoons, cups (5mL = 1 teaspoon, 15mL = 1 tablespoon).
* 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*”. You will be put into a group by chance (like flipping a coin/picking number from a hat) by a computer. Neither you nor the researcher will choose what group you will be in. (OR - The researcher will know what study group you are in, but you will not know.) This process of assigning study groups is done to help researchers look at study results fairly. The study doctor can find out your study group if needed quickly for your medical care.
* A placebo looks like the experimental product but does not include any medicine. It will have no medical effect on you.
* 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.
* If a pregnancy test for a minor female is positive, only she will be told (not her parent/parents)

**HIV and Hepatitis Testing** -Include only if there is HIV testing as part of the protocol

As a part of this study, you will be tested to determine whether you have antibody to HIV, the virus responsible for Acquired Immune Deficiency Syndrome (AIDS). This test is not conclusive but is a screening test. If this test is positive, you will need further testing and counseling regarding risks and precautions. It is required by law that any positive HIV and hepatitis test results be reported to the Colorado State Department of Health along with your full name, date of birth, sex, address and phone number) within 7 days. It is the duty of state and local health officers to conduct investigations to confirm the diagnosis and sources of HIV infection and to prevent transmission of HIV. Such investigations, done by authorized personnel, may include: reviewing relevant medical records and/or performing follow-up interviews (with persons knowledgeable about the case) to confirm diagnosis and to investigate possible sources of infection, materials possibly contaminated with HIV and persons potentially exposed to HIV. Such review of records may occur without patient consent and will be conducted at times and with notice as is reasonable under the circumstances.

Include the following section if there will be genetic testing. If whole genome sequencing will/may occur, this must be specifically stated, e.g., “The research might include whole genome sequencing (determining the order of all of your genes, the DNA in your genetic code).

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**

(This section should be included if study is subject to ICH-GCP per sponsor; else delete)

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
* 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

This section should include all reasonably foreseeable risks and discomforts that the subject may experience as a participant in this research. Consider physical, psychological, etc. as well as the likelihood (in lay terms, e.g., ‘1 in 1000 people’ etc.) and magnitude of each possible harm.

Include as well: **Risk of loss of private information**: Participation in this study involves the possible risk of loss of confidentiality of your study information.

AND

Include the following risks as relevant to your research, else delete:

**Radiation Risks:** The more radiation you receive during your life, the greater the risk of causing changes to the cells in your body or of having cancerous tumors. The radiation from this study is not expected to greatly increase these risks, but the exact increase in such risks is not known. Women who are pregnant should not receive unnecessary radiation and should not participate in this study.

**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.

Unknown Risks: There may be risks to study participation that are not known.

**Reproductive Risks**

If you become pregnant, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus. These risks, if any, are currently unclear.

You should not father a baby while taking part in this study because the drug being tested in this study, *<insert name of the drug>,* could affect an embryo or fetus. If your partner is able to become pregnant, one or both of you must use some form of effective birth control. This may include:

* Not having vaginal sex (abstinence)
* Taking birth control pills orally
* Having birth control shots or patches such as Depo-Provera
* Surgical sterilization (hysterectomy or tubal ligation or vasectomy)
* Use of an intrauterine device (IUD)
* Use of diaphragm with contraceptive jelly
* Use of condoms with contraceptive foam
* Use of diaphragm with condoms (“double barrier”)

You and your sexual partner should continue using birth control until you have stopped taking the study drug for XX months after you have stopped taking study drug.

If you think that you have fathered a baby while taking the study drug or within X months after you have stopped taking the study drug, inform the study doctor immediately.

**OR**

The study drug could affect your sperm and could possibly harm a child that you may father while on this study. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study. Medically acceptable contraceptives include surgical sterilization or a condom used with a spermicide.

**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.

If your research may yield clinically relevant research results, include this section:

Clinically Relevant Research Results

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers <will/will not> contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

**BENEFITS**

If there is possible direct benefit to the subject:

It is possible that you may benefit from being in this study. However, there is no guarantee that your condition will improve; it may stay the same or worsen. However, the information learned from this study may help other people with this disease in the future. Add, if applicable: Even if the study drug helps you, it will not be available to you after the study is over.

Or

If there is no possible direct benefit to the subject:

There is no direct benefit expected for you from being in this study. However, the information learned from this study may help other people with this disease in the future.

**ALTERNATIVES TO STUDY PARTICIPATION**

If there is no medical or other care alternative, state simply: The alternative to being in this study is to simply not participate.

Or

You do not have to participate in this study to receive treatment for your condition. There are treatments such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (List any specific medications or treatments that the subject might choose as an alternative to participation. For example, if the study involves a drug that is FDA-approved, an alternative may be to take the approved drug without participating in the study.Add if applicable: 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**

Subjects must be informed of any **additional** costs they may incur while participating in the study. If there are no additional costs to the subject, the consent form must state that. If the subject’s insurance is to be billed for procedures and visits that are considered standard of care, the subject must be informed.

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

Include as applicable: 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.

**PAYMENT (modify as applicable)**

You will not receive payment or reimbursement for your participation in this study.

Or:

You be paid $XX for each completed study visit (or table breaking down amount per visit)

A payment schedule that best fits your needs will be agreed upon at study enrollment. If you do not complete all study visits, you will be paid for the visits you completed.

With pre-approval from the sponsor, you may be reimbursed for travel expenses. The study sponsor may offer a travel agent or other vendor to assist you in travel arrangements and/or reimbursement. Please see your research coordinator for more information.

Must include if subject receives payment:

Important Tax Information

It is important to know that any payment for participation in a study is considered taxable income, regardless of the amount or form of payment, including check, cash, gift card, gift certificate, money order, or non-cash items. National Jewish Health is required by the Internal Revenue Service to report any payments that exceed $600 per person per year. If you are Nonresident Alien, for tax purposes, all payments made to you, including those for your participation in this study, are subject to a 30% tax withholding.  All withholdings and payments will be reported to those in charge of taxes (IRS) by NJH.  Reimbursement for expenses you have already paid are not considered income and are not taxable. You may be required to complete a W-9 form to provide accurate information for this purpose. However, patient confidentiality will be protected in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). Please contact your coordinator if you do not wish to be paid for your study participation.

Add if biospecimens are collected for this study (modify as appropriate):

Your biospecimens, with or without identifiers, may be used to develop products for commercial profit and it is/is not our intention for you to share in this profit.

**COMPENSATION FOR INJURY**

If you have an injury while you are in this study, you should call the study doctor immediately. Contact numbers are listed on page one of this consent form.

By signing and dating this consent form, you have not given up your legal rights.

Add for all NIH-funded studies, investigator-initiated studies, foundation-funded studies and extended compassionate use studies.

The study staff can help arrange to get you medical care if you have an injury that is caused by this research. National Jewish Health does not offer financial compensation or payment for injuries due to participation in this research.

Add for industry sponsored protocols

In the event of an injury or illness resulting from your participation in the research study, your study doctor can help arrange for you to receive appropriate health care, including first aid, emergency treatment and follow-up care either at National Jewish Health or another appropriate health care facility. In accordance with general NJH policy, we make no commitment to provide free medical care or other compensation for injury or illness resulting from your participation in this study. Medical treatment, paid for by the study sponsor, will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the study doctor will determine if your injury or illness is research-related. The term “research-related injury” means physical injury caused by medications, devices, interventions, procedures, or tests required by the study which are different from the medical treatment you would have received if you had not participated in the study.

The sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, or your negligence or willful misconduct. In addition, the sponsor will not pay for expenses that result from National Jewish Health’s negligence, misconduct or failure to follow the study protocol or the study doctor, study staff or an employee of the institution’s negligence, misconduct or failure to follow the study protocol. If the cost of treating your research related injury was incorrectly billed to your insurance company or a government program by National Jewish Health, the payment will be returned and the sponsor will be billed.

If you experience a research-related injury that requires the sponsor to pay for your medical expenses and you are a Medicare recipient, you will be asked to provide the sponsor with your name, date of birth, gender and Medicare number for Medicare reporting requirements.

**CONFIDENTIALITY**

National Jewish Health has rules to protect information about you. 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.

Scientists at National Jewish Health work to find the causes of and cures for disease. The data and specimens (tissue, blood) collected from you during this study are important. If you join this study the data and specimens given by you to the investigators for this research no longer belong to you. If data and specimens are in a form that identifies you, National Jewish Health or other organizations involved in this study may use them only in a manner consistent with this form and with Institutional Review Board approval.

Include as applicable: 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

National Jewish Health has rules to protect information about your health. Federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA), also protect your privacy. This part of the informed consent form tells you what health information about you may be collected in this study and who will use, share, copy and disclose it.

The institutions and healthcare providers involved in this study include:

* National Jewish Health
* If applicable, use this space for other collaborating/affiliated institutions only, such as University of Colorado, Saint Joseph Hospital, etc.

We cannot do this study without your permission to see, use and give out your health information. You do not have to give us permission. If you do not, however, then you may not join the study. We will see, use, share and copy your health information only as described in this form and in our Notice of Privacy Practices; however, people outside National Jewish Health may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your health information keeps it confidential – but we cannot guarantee that your health information will not be re-disclosed.

The use and sharing of your health information has no time limit. You can withdraw your permission to use and share your health information at any time by contacting the study doctor in writing at the address listed on page one. If you do withdraw your permission, your part in this study will end and no further health information about you will be collected. Your cancellation would not affect health information already collected for the study.

The study doctor (or staff acting on behalf of the study doctor) will use your health information for the research outlined in this consent form. They may also make all or some of the following health information about you collected in this study available to:

* Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
* The Biomedical Research Alliance of New York (BRANY) IRB OR List the name of the IRB of Record
* NJH HRPP/Research Regulatory Affairs Office in conjunction with the NJH Privacy Officer
* The study doctor and the rest of the study team (including collaborators outside of NJH)
* If study is funded: <Insert sponsor name>, who is the company paying for this research study and its affiliates
* Officials and authorized personnel at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in medical journals or medical magazines, but we will always keep the names or other information that could identify you private.

You have the right to request access to your personal health information related to the study. If applicable add: To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

[Include if the research may involve whole genome sequencing.]The research might include whole genome sequencing (determining the order of DNA building blocks (nucleotides) in your genetic code).

[if applicable] Some of the research procedures involve genetic testing or the use of your genetic information. Your genetic information will/will not be released to others.

Information about you that will be seen, collected, used and disclosed in this study:

[check all that apply]

[ ]  Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)

[ ]  Your social security number for payment purposes

*[ ]*  Your Medicare number for reporting requirements if you have a study related injury and are a Medicare recipient

[ ]  Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results

[ ]  Data from Research-related activities and procedures

[ ]  Data from Biologic samples such as Blood/Urine/Saliva

[ ]  Psychological and mental health test results

[ ]  Information related to Alcoholism or Alcohol/Drug abuse

[ ]  Testing for or infection with diseases reportable to the Public Health department, including but not limited to: Human Immunodeficiency Virus (HIV), hepatitis (all forms) tuberculosis, or other sexually transmitted diseases

[ ]  Testing for sickle cell

[ ]  Data from future Genetic research if you opt in

[ ]  Other (please specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Collection of Identifiable Private Information or Identifiable Biospecimens (choose one of the following options, and delete the other):

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.

Certificate of Confidentiality (if NIH/CDC/FDA funded, or as applicable-else delete):

To help us protect your privacy, the study doctor has obtained/applied for a Certificate of Confidentiality from the Department of Health and Human Services. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal agency. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

**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.

If FDA regulated study, include: If you choose to withdraw from the study early, it is important to know that data collected up until the time you withdraw will remain part of the study database and cannot be removed, and will still be used and given to others.

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. You may be taken out of the study even if you do not want to leave the study. 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 the study doctor at the phone number listed on page one.

If you are in an emergency, make sure you tell the emergency staff that you are in this study. They can contact the study staff for information.

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.

**STATEMENT OF CONSENT**

By signing this form, I confirm the following:

* I have read all of this consent and authorization form.
* I have been told about the risks of being in this study.
* 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.

**Use for Adult Subjects Capable of Consenting for Themselves:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

I have explained the study procedures and risks to the study subject and answered all questions related to the procedures that the subject asked. I have also explained to the subject that he/she can refuse to participate in the study at any time.

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

**Use for Legally Authorized Representatives (LAR) giving permission for adult subjects who are incapable of consenting for themselves**

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**Printed Name of Adult Subject**

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

I have explained the study procedures and risks to the LAR and answered all questions that were asked regarding this study. I have also explained to the LAR that they can change their mind at any time regarding the subject’s participation in the study.

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

**Use for Parent/Guardian(s) giving permission for subjects under 18 years old (minors):**

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**Printed Name of Minor Subject**

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**Parent/Guardian**: Name (Printed) Signature Date

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**Parent/Guardian**: Name (Printed) Signature Date

(if two parent/guardian signatures are required by IRB)

I have explained the study procedures and risks to the parent/guardian(s) and answered all questions that were asked regarding this study. I have also explained to the parent/guardian(s) that they can change their mind at any time regarding their child’s participation in the study.

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