BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

NAME OF CLINICAL CENTER
SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: COPDGene 10.0 - Genetic Epidemiology of Chronic Obstructive Pulmonary Disease (The COPDGene Study), Phase 4
Protocol #: COPDGene 10.0
Sponsor: National Heart, Lung and Blood Institute
Principal Investigators:
Institution:
Address:
Telephone:

KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to participate in this research study because you have participated in the COPDGene study in the past. You are being invited to take part in the fourth phase of COPDGene.

The following table is a brief 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 research study to evaluate the long-term effects of Chronic Obstructive Pulmonary Disease (COPD) and cigarette smoking, how COPD may change over time, and identify subtypes of COPD and their genetic factors.
Experimental	You will not receive any experimental drugs or procedures as part of this study. The study involves an additional visit, 15 years after you started the COPDGene study, to assess your health and how your lungs are working.
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 has been ongoing and you will continue to be included in the project over the next five years or longer if you agree. During that time, you will have about 1-3 study visits, periodically receive calls or emails to provide updates about your health, and you may receive newsletters.
Procedures	The main procedures in the study include: • Breathing Tests (Spirometry and Diffusing Capacity) • CT scan of the chest • Six-minute walk • Blood samples • Questionnaires
Risks	There are only minimal potential physical risks to you expected as part of this study.
Benefit	There is no direct benefit to you from taking part in this study. However, the study results may help people in the future and you

	may learn about your own health from the study procedures.
Confidentiality	There are provisions in place 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 COPDGene 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 staff and study doctor 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 physician(s). If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

The National Heart, Lung and Blood Institute, the sponsor of this study, is providing funds to National Jewish Health (NJH)) to conduct this research study. [Name of Clinical Center] where you will have the study visit is receiving funds from NJH.

PURPOSE OF THE STUDY

The purpose of this study is to learn more about chronic obstructive pulmonary disease (COPD) and cigarette smoking and how COPD may change over time. The additional information obtained during this fourth phase of the study may help us change the way that doctors diagnose COPD and may identify new markers that influence the development and progression of COPD. We will also assess genetic and other factors that are associated with COPD and other smoking-related disorders such as cancer and heart disease, as well as aging and other diseases not related to cigarette smoking.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 3500 subjects are expected to participate in this phase of the study at 19 research sites in the United States.

This is a long-term study and your participation is expected to continue over the next five years and possibly longer.

STUDY PROCEDURES

Contact and Personal Information:

You will be asked to provide or update your date of birth, address, home and cell phone numbers, social security number and email address. You will be asked to provide a government issued identification to confirm your identity in order to make sure that we are continuing to collect information from the correct person.

We will also collect contact information on two other people, one of whom is a next of kin, and the other a relative or close friend, one of whom is not living with you. We need this information to maintain contact with you in case you move or change your phone number. You will be asked to designate one or more individuals as your next of kin or personal representative for us to contact in the event of your death.

We will ask you the name and address of your primary physician and pulmonary (lung) doctor (if you have one) so we can send them the results of this study that may be of medical importance to you. We will provide you with a letter to share with these individuals that explains your involvement in the study and their participation. We strongly urge you to give a copy of this letter to your secondary contacts, next of kin and treating physicians.

We will send your breathing test, blood count, and chest CT study results to you after the visit so that you may share it with your physicians. If data from your study results are felt to possibly

be clinically significant (results from the Hospital Anxiety and Depression Scale (HADS), blood count or chest CT scan) they will be sent to your personal healthcare provider.

Your name, address, date of birth, phone numbers, next of kin and their contact information, and your social security number will be securely transmitted to the Data Coordinating Center at National Jewish Health, where it will be stored securely and separately from the other data collected in the study. This information will be used to check your vital status using multiple sources possibly including, but not limited to, the Social Security Death Master File, National Death Index, general internet searches, and obituary postings, in case we cannot reach you or one your additional contacts. We will get your death certificate and medical records to determine why you died. The information will also be used to identify geographic factors including air pollution and other environmental exposures that may have affected your lungs.

We may also use your social security number to possibly obtain information about your healthcare and costs of health care from Medicare along with commercial insurance and other administrative databases. Information regarding the addresses where you have lived will be de-identified so they cannot be linked to you, but they will be shared with researchers who are studying the effects of environmental exposures on disease.

In the event that [Name of Clinical Center] is unable to perform follow up contacts or visits, the COPDGene Administrative Core will work as an agent for [Name of Clinical Center]. This means you may be contacted by the COPDGene Administrative Core at National Jewish Health to follow your health and vital status, as well as to schedule future visits if additional funding is obtained to continue the study. You may also be transferred to another COPDGene clinical center for some aspects of the COPDGene study.

Informant Interview: In the event of your death, we will contact one of the people that you designated as your next of kin, close friend or personal representative, and your treating physician for information about the events surrounding your death. Your treating physician will be contacted to obtain medical records related to the events and illnesses associated with your death.

You will be asked to sign a release of medical records so we may contact doctors and hospitals that have provided medical care to obtain information about your medical condition and other medical problems you may have or develop in the future.

You will be asked if you are currently participating, expect to participate or have in the past participated in other research studies about lung disease. If you participated in other studies, we would like to obtain information about your results in the other studies to see if there is an association with those results and your results in the COPDGene study.

Questionnaires:
You will be given several questionnaires that will ask about symptoms of lung disease including shortness of breath, family history, medical conditions, symptoms of anxiety and depression (called the HADS), medications you are taking, your current and former addresses and work history, economic issues that may impact care of COPD, menopausal history if you are a woman, exacerbations of your COPD (if you have COPD), health-related quality of life, COVID-19 infections and vaccinations, physical activity, and cognitive questions. We will also be asking questions related to smoking and the use of e-Cigarettes and vaping. In the future, we may also invite you to sign a separate consent to have your biopsy or surgery tissue specimens sent to us for analysis.

Some of these questions we ask you are taken from standardized commonly used questionnaires. You will be asked to complete the questionnaires by yourself or the study coordinator will ask you the questions either on the computer or using a paper and pen. It will take between 1 and 2 hours to complete all the questionnaires in this study.

Blood Sample: About 3 and a third tablespoons (1 tablespoon is the same as 15 ml) of blood will be removed by putting a needle into a vein in your arm or the back of your hand. This is the standard method used to obtain blood for testing. We may perform a whole genome sequencing analysis on your new or previously collected blood sample. Usually, researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to diseases. Your blood samples will also be used to measure proteins and other blood factors that may be related to COPD and other medical conditions.

Breathing Tests (Spirometry and Diffusing Capacity): Spirometry is a breathing test that measures how much air you can blow out of your lungs and how fast you can blow out that air. You will be asked to forcefully blow into a lung-testing machine (called a spirometer). This test will be performed at least three times to get reproducible results. After the test is done, you will be given an inhaled medication (albuterol) to open up your air passages. After that medication, you will do spirometry again to measure your lung function. Before you are given albuterol, you will be asked some questions to assure your safety when you take this medication.

We will also perform a diffusing capacity test that measures how well a test gas (small concentration of carbon monoxide) is transferred through your lungs and into your blood. For this test you will be asked to take a deep breath of the gas mixture, hold it in your lungs for 10 seconds, and then blow it out. You will perform this test at least two times to get reproducible results.

Physical Assessment: Your height, weight, arm span, and waist circumference will be obtained. Your blood pressure will be measured three times. A probe will be placed on your finger to measure the amount of oxygen in your blood and heart rate while you are resting and breathing room air. If you use oxygen, your oxygen will be removed for 10 minutes so that we can check your oxygen level while you are breathing room air while sitting and resting in a chair. If your oxygen level falls to 82% or less or if you become short of breath your oxygen will be replaced.

Six-Minute Walk Test: You will be asked to walk for 6 minutes on a level surface to see how far you can go. If you use oxygen when you walk, you will use it for this test. You will be asked some questions to assure your safety before performing this test. Immediately following and one minute after the six-minute walk test, your heart rate and oxygen saturation will be measured using a pulse oximeter.

Sit to Stand Test: This is a test which sees how many times you can go from sitting to standing in 30 seconds without using your hands. This test measures your leg strength and endurance.

Chest CT Scan: At the visit, you will have a chest CT scan. Before the CT scan, we will ask you about recent bronchodilator medication that you have taken for your lung disease. For the CT scan, you will lie on a table and the table will move through the middle of an x-ray machine that looks like a large round donut. You will be asked to lie quietly and take a deep breath in and hold it for the scan. Then you will be asked at the end of a normal breath to hold your breath for a second scan.

Pregnancy Test: Women who are pregnant are temporarily not eligible for this study. If you are capable of being pregnant, you will have a urine pregnancy test before the chest CT scan to be sure you are not pregnant. Pregnant subjects will be re-scheduled for a visit when confirmed to be not pregnant.

Medical Record Review: The following test results may be obtained from your medical record if records are readily available: high resolution CT scan, breathing tests, oxygen and carbon dioxide levels, bone density tests, and medical information and pathological reports for cancers you have had.

Health Care Utilization: Information regarding your health care utilization and costs, if you have Medicare, may be obtained from the Centers for Medicare and Medicaid Services (CMS) databases. Once we receive Medicare information, your identifying information will be removed. Other sources of healthcare utilization including commercial insurance databases and other administrative data may also be used but your personal identifiers will not be shared outside of the study's data coordinating center.

Death Certificate Release: In the event of your death, your [Name of Clinical Center] research coordinator and/or the central study coordinator from National Jewish Health will obtain your Death Certificate from the State Office of Vital Statistics. Death Certificates will be used to gain information on the cause of death and these records will be held centrally at National Jewish Health.

Disclosure of Participation in a Research Study: Your participation will also be disclosed to your designated next of kin, close friend or personal representative who we may contact in the event of your death or if we are unable to contact you. We will provide you with a memo to share with these individuals that explains your involvement in the study and their participation.
Your participation in the COPDGene research study will also be disclosed to your physician(s) if there are clinically significant findings that may impact potentially your health care.

Follow-Up Contacts: We will continue to contact you by regular mail, email, or telephone up to four times per year for the next ten years. We will ask about your health and whether you have changed your address or phone numbers. We may also contact you at other times in the next ten years to invite you to participate in other research studies about lung disease and other diseases, and to update you about new findings in this COPDGene study and other COPD studies. We plan to apply for additional funding in the future to follow you for a longer period of time. We will ask you if you want to be a part of future extensions of the COPDGene study.

Internet Search: Use of publicly available internet sources will be used in the event that we are unable to contact you and/or in the event of your death. The [Name of Clinical Center] coordinator and/or a central study coordinator from National Jewish Health will use the personal information you provided us to search for updated contact information (home addresses, phone numbers, and email addresses) only in the event that we are unable to contact you. Publicly available death records will be searched only in the event of your death or if death status is unknown.

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. In previous phases of the COPDGene study we have collected your DNA (genetic

material) and analyzed it, including whole genome sequencing, for information about your genes. We will continue to use this genetic information as we study risk factors for COPD and other diseases.

Your collected samples will be destroyed when they are no longer needed. To help protect your privacy, your samples 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. At this time, we do not have plans or intentions to give you the results of the genetic testing or other laboratory studies, which will be performed in research rather than clinical laboratories. However, if there are findings from this work or from other laboratory studies in the future that could be clinically important, we may contact you and offer you the choice to receive that information.

YOUR RESPONSIBILITIES

As a participant 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.
- Tell the study research coordinator all medications that you are taking (including inhalers, prescription, over-the-counter, vitamins and herbal supplements).
- Tell the study staff any time you do not feel well.

RISKS AND DISCOMFORTS

Risks of Blood Draws: Risks associated with drawing blood from your arm include some pain when the needle is inserted. There is a slight risk of bruising and a very small risk of infection at the place where the needle entered your arm. Some people may experience lightheadedness, nausea or fainting. Treatment will be available if this occurs.

Risks of Breathing Tests: You may become temporarily short of breath or experience chest tightness while doing the breathing tests (spirometry and diffusing capacity). Occasionally after using the albuterol inhaler a temporary sensation of "heart racing" and shakiness may develop. Treatment will be available if this occurs.

Risks of Stopping Your Oxygen: If you use supplemental oxygen, you may become short of breath when your oxygen is temporarily stopped. We will monitor the oxygen level in your finger and if it gets too low or you get short of breath, your oxygen will be restarted.

Risks of Six-Minute Walk Test and Sit to Stand Test: You may become short of breath, tired or experience chest tightness while doing the walking test. Treatment will be available if this occurs. There is a small risk of abnormal blood pressure (up or down), fainting, disorders of the heartbeat (too fast, too slow, or irregular), and heart attack. To reduce the risk of these complications, you will be asked questions about your medications, medical condition, and potential heart problems before doing these tests.

Risks of Chest CT Scans: You will be exposed to radiation in the CT scanner. The average amount of radiation exposure during the chest CT scan is approximately 3.5 mSv (mSv stands for millisievert, which is a measure of the dose of low levels of radiation.) The average amount of background doses of radiation that the general population is exposed to in the United States is 3 mSv per year. Thus, the average amount of radiation you will receive is equivalent to about one and one third years of normal background radiation. The more radiation received over the course of a life, the greater risk of having cancerous tumors or of inducing changes in genes.

The changes in genes possibly could cause abnormalities or disease if you have offspring in the future. The radiation in this study is not expected to greatly increase these risks, but the exact increase in such risks is not known. You will be asked questions to determine if you might be pregnant. If you might be pregnant, we will check your urine to make sure you are not pregnant. Women who are pregnant may not participate in the study until they are confirmed to be not pregnant.

The chest CT scan can provide important clinical information, such as the presence of lung nodules, which may require additional medical testing. The investigators in this study feel it is important to send the results of your chest CT scan to your personal physician as well as to you.

Depression and Anxiety Questionnaire: This questionnaire may indicate that you may possibly be depressed. If your responses to this questionnaire indicate you may be depressed, we will tell you and we will also inform your personal physician. You will be asked the name, address and phone number of your doctor so we may contact him/her.

Risks of Research: This study will provide information about your genetic material (DNA). DNA isolated from your blood as well as other blood samples will be shared with other scientists for research studies. These investigators will not be provided with any information that can identify the DNA, or blood as yours. The blood and DNA results from this study will be analyzed in a research setting rather than in a clinical laboratory, so we do not currently plan to tell you or any other individual about your specific genetic or blood results. If in the future there is important new information that might affect you, we may contact you to offer that information. You can decide at that time if you wish to receive the information.

I understand that by signing this consent I agree that my new and previously provided blood samples will be stored in the COPDGene Study central repositories at Brigham and Women's Hospital and Johns Hopkins University indefinitely for use by study investigators in studies of COPD and other medical and scientific problems. In addition, medical and other information collected for this study including questionnaires, blood test results, breathing tests, six-minute walk test, sit to stand test, addresses and chest CT scan will also be stored for future analysis. Your personal identifying information will not be given to other investigators. As required by the National Institutes of Health, your blood samples and medical information will become an important national resource for genetic and other studies of COPD and other medical and scientific problems. Your genetic data may be used for future research on any topic and shared broadly in a manner consistent with all applicable federal and state laws and regulations. Your genetic data will be shared with other investigators, but no one will be permitted to publicly release information about your identity. The use of your blood samples, medical information and tests will be monitored and shared only with investigators who agree to maintain confidentiality and respect your privacy. Your identity will not be available to other investigators when sharing your blood samples and medical information and tests. However, a possible risk of study participation is the loss of confidentiality about your medical information.

The blood samples and other study information and tests taken from you may be used for the development of one or more research, diagnostic, or therapeutic products. Blood provided by you during the course of the study may be valuable for scientific research, or testing purposes for development of a new product that may be distributed commercially. There are no plans to share with you any financial compensation should this occur. By signing this consent form, you authorize [Name of Clinical Center], members of its Professional Staff and other study investigators to use your blood for these purposes.

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 risk 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
If any of the clinical test results are potentially important to you from this study, you will be told about them and they will be sent to your physician. .

BENEFITS
There are not expected to be any benefits to you from this study. The results may be important to others in the future. We cannot promise any benefit to you or others from your participation in this research.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to participate in this study. You can choose to not participate and there will be no change in your medical treatment or care.

COSTS OF PARTICIPATION
There are no costs to you if you participate in the study.

REIMBURSEMENT
You will receive $200 for your time and effort participating in this study. If you have already received $25 for completing the questionnaires over the phone, you will receive the remaining $175 for coming in today. You will receive this by [method of payment] at [time of payment].

Tax law may require the [Name of Clinical Center] 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 received $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you receive from the study.

You will not receive payment of any kind for your information and specimens (even if identifiers are removed) or for any tests, treatments, products or other things of value that may result from this research study.

COMPENSATION FOR INJURY

For medical emergencies, call 911. If you become ill or are hurt the study visit, tell 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.

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;
- The injury was the result of a failure to follow the study protocol or instructions or misconduct by the study staff.

No other compensation will be offered by the sponsor or (Insert Clinical Center Name) 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. Medical records, which identify you and the consent form signed by you, by the 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the NIH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

If you take part in this study, you will be assigned a unique subject code to help protect your privacy. Your study records and study samples will be labeled with this code that does not directly identify you. The study site staff securely stores the linking code between your name and study information.

A description of this study will be available on *http://www.ClinicalTrials.gov*. 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:

- National Jewish Health; study sponsor staff
- 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
- 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.

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 that are responsible for protecting your rights.

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).

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 staff or 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. The IRB is a committee that reviews research studies to help protect the rights and welfare of study subjects.

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.

Subject: Name (Print)	Signature	Date

Person Obtaining Consent: Name (Print)	Signature	Date