Study ID: STUDY-19-01121
Form Version Date: [09Nov2023]

STUDY INFORMATION:

Study Title: A SMART Approach to Treating Tobacco Use Disorder in Persons with HIV (SMARTTT)

Study site(s): The Yale Center for Infectious Diseases (formerly Nathan Smith Clinic and Haelen Center)

BH (Bridgeport Hospital) Primary Care Infectious Disease Clinic

Lead Researcher (Principal Investigator): E. Jennifer Edelman, MD, MHS

Steven Bernstein, MD

Physical Address: The Yale Center for Infectious Diseases, 200 Orchard Street, New Haven, CT 06511

BH Primary Care Infectious Disease Clinic, 226 Mill Hill Avenue, Bridgeport, CT 06110

Mailing Address: 367 Cedar St., ESH-A, Rm 302, New Haven, CT 06510

Phone: 203-737-3347

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care within the Yale-New Haven Health System. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to compare different strategies, involving medications (nicotine replacement therapy, varenicline, and/or bupropion) and contingency management to help individuals with HIV stop smoking. Contingency management is a behavioral treatment that uses rewards to help individuals engage in healthy behaviors. In this study, if you are assigned to receive contingency management, you will have the potential to receive rewards for not smoking cigarettes. Although nicotine replacement therapy, varenicline, and bupropion are medications that are approved by the U.S. Food and Drug Administration to help people to stop smoking, the lead researchers do not know how well they work in combination with contingency management and this is part of what is being studied.

If you choose to take part you will be asked to:

- Meet with the research assistant at baseline, 12 weeks and 24 weeks to complete research

assessments

- Participate in 11 visits with a clinical pharmacist, each lasting 20 minutes, over the course of 24 weeks who will prescribe medications for you to help you stop smoking.
- If you are randomized to receive contingency management, you will be offered rewards for not smoking during your visits with the clinical pharmacist over the course of 24 weeks.
- All of your sessions will take place at the clinic where you normally receive your HIV care or may occur remotely.
- At 12 months, the research assistant will review your medical chart to follow up on your progress
- Undergo carbon monoxide breath tests and fill out study questionnaires at each visit with the research assistant if you report that you are not smoking. In addition, if you are in the contingency management group, you will undergo carbon monoxide breath tests at each contingency management visit to confirm you are not smoking or be asked to provide a close contact to verify smoking status.
- There are no costs to you for participation in the study.
- You will be provided compensation for your time and effort spent with the research assistant.

If you choose to take part, the main risks to you are possible side effects to nicotine replacement therapy, varenicline, and/or bupropion.

You may benefit from taking part in this research. A potential benefit is if you are able to stop smoking, which may greatly improve your overall health.

Instead of participating in this research, you may 1) not participate or 2) ask your HIV doctor for help to stop smoking.

If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have been diagnosed with HIV and smoke cigarettes. For this project, participants must smoke cigarettes regularly.

In order to participate in this study, you must have a diagnosis of HIV, be at least 18 years old and be free of any major medical, surgical, or psychiatric condition based on review of your medical record that interfere with study participation. In addition, you will not be eligible to participate if you only use non-cigarette tobacco or nicotine products, are currently taking medications to help you stop smoking, are pregnant, nursing or trying to conceive (for women only), unable to provide at least one contact for a friend or family member, or live out of state.

Your participation in this research study is expected to last 24 weeks.

There are 100 people expected to take part in this research study at YNHHS (Yale New Haven Health System) clinics and 320 people to take part across all sites.

Funds for conducting this research study are provided by the National Cancer Institute.

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.

DESCRIPTION OF WHAT IS INVOLVED:

All participants will be asked to meet with a research assistant either in-person at The Yale Center for Infectious Diseases (formerly Nathan Smith Clinic and Haelen Center) or the BH Primary Care Infectious Disease Clinic or by video conference or telephone to complete questionnaires.

Participants assigned to both groups will be invited to meet with a clinical pharmacist six times either in-person or remotely (video conference or telephone) six times within a 12-week period to start nicotine replacement therapy, check on progress with stopping smoking and to discuss any potential medication side effects. The clinical pharmacist will initially prescribe 12 weeks of nicotine patches, with gum, lozenges, an inhaler or spray based on how much you smoke and your preferences. You will fill the prescription through your usual pharmacy of choice. Additional medication will be prescribed as you need it during the follow-up visits. If you are also receiving contingency management from the clinical pharmacist, you will also be eligible to earn rewards, if you do not smoke based on your report and carbon monoxide breath testing. For each single session, you may draw gift cards in the amount of $5 to $100.

If you report that you are not smoking tobacco, it will need to be verified. You can either complete an exhaled carbon monoxide test or provide contact information for a household member or other close contact who can confirm that you have stopped smoking.

Twelve weeks after starting the study, you will meet with the clinical pharmacist to determine whether you should continue your treatment or change treatments based on whether or not you are smoking:

- If you have stopped smoking based on what you tell us and carbon monoxide breath test, you will continue with the same treatment you started with (either nicotine replacement therapy or nicotine replacement therapy plus contingency management) for another 12 weeks. The Food and Drug Administration has made suggested changes to the labeling guidelines, and treatment with nicotine replacement therapy may be used for up to 24 weeks.

- If you continue smoking based on what you tell us and carbon monoxide breath test, you will be reassigned at week 12. You will be randomized to either switch medications from nicotine replacement therapy and will be offered varenicline (Chantix®) or bupropion (Zyban®), an FDA approved medication to help people stop smoking cigarettes, or to receive an increase in potential rewards with contingency management.
- All participants, regardless of which treatments they are receiving and their initial response to treatment during the first 12 weeks, will continue to meet with the clinical pharmacist as before to check on your progress with stopping smoking and monitor any side effects to the medications. The study team will continue to be monitor your progress.
- The treatment phase of the study ends at after 24 weeks. At this point, the study team will discuss treatment options with you.

At 12 and 24 weeks, you will also meet with the research assistant to conduct questionnaires and complete the carbon monoxide breath test if you did not do this with the clinical pharmacist. You will be asked questions about your behaviors including your smoking and other substance use, symptoms, treatment services, adherence to tobacco treatment medication, and satisfaction with the study's activities. The study team will also collect a breath test to check your carbon monoxide level to give us information about how much you are smoking. To protect your safety, any in-person visits with either the clinical pharmacist or the research assistant will require you to wear a mask and maintain a distance of six feet. In addition, all surfaces and equipment will be wiped down before and after your visit. The study team will also collect information on your blood test results through the electronic medical record. At the end of 24 weeks, your active participation is complete.

At 12 months, the research assistant will review and collect lab results from your medical chart, including CD4 count, HIV viral load and other measures of your health (hemoglobin, AST, ALT, albumin, white blood cell count, platelets, hepatitis C status, creatinine), body mass index, and treatment services to address your tobacco use. You do not need to be present for this.

Because this project involves the use of medications, it is necessary that the study team make a note of your participation in the electronic medical record and when you complete study visits to address your smoking. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown. Also, prescriptions for nicotine replacement therapy and, if indicated, varenicline and/or bupropion will also be noted in your electronic medical record as these will be prescribed for you to get from the pharmacy.

In order to comply with social distancing guidelines and safety recommendations, visits may take place over the phone or via HIPAA compliant video conferencing.

Randomization

No one, not you, or anyone from your medical team or from the research team will be able to choose what group you are assigned to. You will be randomly assigned, by luck of the draw or chance, to one of two groups of participants. Depending on the group to which you are assigned, you will receive one of the following two types of treatments: Group A) Nicotine replacement therapy or Group B) Nicotine replacement therapy with Contingency Management.

The study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study team will choose what experimental study treatment you get. You will have a one to one chance of being given each experimental treatment.

Since you are participating in a research study that involves medications with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. If you are pregnant based on information you provide or a pregnancy test, you will not be eligible to participate. You should not participate if you are breastfeeding.

Should you become pregnant, regardless of the outcome, the sponsor may ask for information on your pregnancy, even if you are withdrawn from the study. Your written consent will be obtained separately in the case that this happens.

USE OF YOUR DATA AND/OR SAMPLES

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select ‘No’ each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____No_____

If you select No, please stop here and move to the next section, **'Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) The researchers can store your data and/or samples in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can't change your mind. So, if you wanted to have your data and/or sample destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.

b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial **ONE** choice below:

I would like my data and/or samples stored anonymously _____

I would like my data and/or samples stored with a link to my identity through the use of a code_____

(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____No_____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____No_____

OUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things: attending study visits and taking medications as prescribed.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

Being in this research study will not lead to extra costs to you.

If you agree to take part in this research study, you will be compensated up to $150 for your time and effort, depending on how many visits you attend. For the first visit, the 12 week visit, and the 24 week visit you will earn $50 at the end of each session. If you are in the contingency management group, you have the potential to earn additional rewards for each session; these rewards will be in the form of a gift card to a local store.

Tax law may require the Yale School of Medicine Finance Department to report the amount of payment you receive from Yale School of Medicine or Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this happens if you receive payments that equal

$600 or more from Yale University or Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be that you are able to stop smoking, which may greatly improve your overall health. In addition, this study will generate new information about clinical pharmacists might be able to best help other people with HIV stop smoking.

POSSIBLE RISKS AND DISCOMFORTS:

The main risks to you if you choose to participate are possible side effects to nicotine replacement therapy, varenicline, and/or bupropion.

Some possible side effects of nicotine replacement therapy are localized skin rash or allergic reaction from wearing the nicotine patch, sleep disturbance of vivid dreams, nausea or indigestion from the use of nicotine lozenges or nicotine gum, dizziness, headache, myalgia, rapid heartbeat, mouth irritation, sore throat, jaw pain, bad taste, hiccups, dental problems.

There is a very small risk of nicotine toxicity, if nicotine replacement products are used in higher quantities than prescribed or from smoking while using the products. Symptoms of nicotine toxicity include cold sweats, fainting, confusion, or pounding heart. The Food and Drug Administration has published new guidelines which suggest that these products are safe to use longer than 12 weeks.

Varenicline may cause nausea in some people, but this goes away over time. You may also experience sleep disturbance or vivid dreams. Less common side effects include indigestion, abdominal pain or gas, fatigue, headache or dry mouth.

Bupropion may cause insomnia, dry mouth, and constipation. Uncommon side effects may include rash, itching or hives. The medicine may also cause dizziness and may also cause some patients to have abnormal behaviors or worsening mood or suicidal thoughts.

There is a risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

You cannot be included in the study if you are pregnant or become pregnant, as the study [drugs could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the study drugs could harm your baby.

Group Risks - Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. Instead of being in this research study, your choices may include 1) not to participate or 2) asking your HIV doctor for help to stop smoking. Your doctor might provide counseling, medications or refer you to the Yale Smoking Cessation Program.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the Lead Researcher for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through the Yale-New Haven Health System will not be negatively impacted.

If you decide to stop being in the research study, please contact the Lead Researcher or the research staff.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask in writing to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The Lead Researcher, the funder or Yale University may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number 203-737-3347.

If you experience an emergency during your participation in this research, call 911.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research, will collect information about your health that includes:

- Research study records
- Records about phone calls made as part of this research
- Records about your study visits
- Medications
- Questionnaires

As part of this study, the research team at the hospital(s) involved in the research will collect your information from your medical records, including:

- Name
- Gender
- Date of birth
- Medical Record Number

- Telephone Number
- HIV / AIDS
- Hepatitis infection
- Sexually transmitted diseases
- Physical exams
- Laboratory and other test results
- Sexual practices
- The diagnosis and treatment of medical and psychiatric conditions
- Tobacco and alcohol use
- Drug use
- Treatments to address tobacco use
- Hospitalizations, Emergency Department visits

During the study the researchers will gather information from you through questionnaires. The study team will also collect information from your electronic medical record. This will include medical and psychiatric diagnoses, medications, visits, procedures and lab test results. This information is being collected so the lead researchers can better assess how treatments in this study impact health outcomes.

During the study, the researchers will gather information by:

- Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV.

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers in the Yale-New Haven Health System who are involved in your care or treatment. The research team and other authorized members of the Yale University workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Yale Human Research Protection Program and the Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Yale University Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Yale University might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Yale University workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.) Information about you and your health which might identify you may be used by or given to:

- The U.S. Department of Health and Human Services (DHHS) agencies and the Office of Human Research Protection.

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Yale School of Medicine, SUNY Downstate School of Medicine and the Icahn School of Medicine at Mount Sinai.

- The Yale Human Research Protection Program and the Yale Human Investigation Committee, the Human Research Protection Program at the Icahn School of Medicine at Mount Sinai and the Institutional Review Board at SUNY Downstate Medical Center (the committees that review, approve, monitor research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- Those providers who are participants in the Electronic Medical Record (EMR) system.

- The Lead Researchers overseeing the study: Drs. E. Jennifer Edelman and Steven L. Bernstein

- The sponsoring government agency and/or their representative who need to confirm the accuracy of the results submitted to the government or the use of government funds: The National Cancer Institute (NCI)

- Health care providers who provide services to you in connection with this study.

- Co-Investigators and other investigators

- Study Coordinator and Members of the Research Team

- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the study

In almost all disclosures outside of Yale School of Medicine you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted

direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. The lead researchers may publish the results of this research. However, your name and other identifying information will remain confidential.

For how long will Yale be able to use or disclose your PHI? Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?

NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to

which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

It is important for you to understand that once information is disclosed to others outside Yale School of Medicine the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also 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 Connecticut Commission on Human Rights and Opportunities at 860-541-3400. This agency is responsible for protecting your rights.

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else

is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect you or others. 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. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

WITNESS SECTION:

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

Signature of Witness	Printed Name of Witness	Date	Time