Comprehensive Home-based Self-management Support for COPD Patients
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NCT04533412
Document Date: 12-23-2022

STUDY INFORMATION:

Study Title: Comprehensive Home-based Self-management Support for COPD Patients

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is to test a new model to improve self-management behaviors and outcomes for people with chronic obstructive pulmonary disease (COPD). COPD patients can benefit from improved self-management behaviors, like consistent use of controller medications, proper inhaler technique, and regular exercise. The research team previously developed a program for participants with asthma: Supporting Asthma Self-Management Behaviors for aging Adults (SaMBA). This trial will adapt the SaMBA asthma study for COPD participants and will be known as SaMBA-COPD.

This study is a randomized control trial. This means that if you agree to participate, the study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the researchers will choose whether you get the Intervention or the Control. You will have an equal chance of getting the Intervention or the Control.

The Intervention Group: Participants who receive the intervention will have visits in-person and or by telephone or video visit with a community health worker (CHW) via Zoom or VSee. The CHW is a person who can help you manage your COPD. Their goal is to help you breathe better and feel better. They will do the following things with you: 1) ask you about your COPD symptoms; 2) make sure you are using your COPD medications correctly; 3) identify the problems that keep you from breathing and feeling better; 4) and help you fix those problems.

Some ways in which the CHW could work with you to fix the problems that keep you from breathing and feeling better include the following: a) provide you with counseling about COPD; b) refer you to a social worker (for example, if you're having problems with your insurance or paying for medications); c) refer you to a pharmacist for counseling about COPD medications; the pharmacist may also suggest giving you a prescription for a medication "emergency pack," which consists of steroid and

antibiotic pills for you to have on hand in case you develop a COPD exacerbation or flare-up; the medications would only be prescribed to you with the knowledge and permission of your doctor; d) refer you to a clinician to get an exercise plan that could help you breathe and feel better; a referral to the clinician would only be made with the permission of your doctor; e) alert your doctor to the problems you're having. The CHW will always talk to about how they want to help you, and you are free to accept or refuse their suggestions. They will only act with your permission.

If you agreed to meeting with the clinician, the CHW would arrange for the meeting to happen at the medical center or by video chat. If you do not have a smart phone, tablet, or computer for video chat, we will provide a tablet for you and you can keep the tablet when the study is concluded. The clinician would evaluate your ability to walk and the strength of your arms by having you perform simple exercises. He/she would then prepare an exercise plan for you to do at home. The CHW would talk with you to make sure that you are doing those exercises correctly.

Dr. Federman and Dr. Wisnivesky will serve as clinicians. Dr. Federman is a board-certified internist who practices general internal medicine. Dr. Wisnivesky is a pulmonologist. Both have done extensive research with the COPD population.

The intervention lasts for 6 months. During those 6 months, the CHW will meet with you and or speak with you by phone or video chat several times. The number of times you meet and or speak would be decided by you and the CHW together. You will select days and times that work best for you to meet and or speak with the CHW.

The Control Group: Participants randomized to the control assignment will receive basic education about COPD from a COPD counselor. The COPD counselor will meet with you in person or by telephone or video call using Zoom or VSee. If you do not have a smart phone, tablet, or computer for video chat, we will provide a tablet for you and you can keep the tablet when the study is concluded. There will be 4 meetings in 6 months at days and times that are convenient for you. The COPD counselor will teach you basics about COPD using a helpful education workbook and will be available to answer your questions. Although the COPD counselors know a lot about COPD, they are not doctors or nurses. If they do not know the answer to your questions, they will suggest that you ask your doctor.

There are no costs to you to participate in this study. You will be compensated $65 for each of the 3 interview visits, but you will not receive any payment for visits made by the CHW. Whether you are in the control or intervention group, we will provide you with an electronic bracelet to count the number of steps you take each day, and a pulse oximeter, which measures the oxygen in your blood. You may keep these materials when your participation in the study has concluded. Also, if we provide you with a tablet, you may keep it when your participation in the study has concluded.

The main risks to you if you choose to participate are feeling discomfort or fatigue during breathing tests and pulmonary rehabilitation, and the potential for the loss of private information.

You may also benefit from participation in this research by developing improved health and self-management behaviors.

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

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you have COPD and have visited the Emergency Department or been hospitalized for COPD related conditions within the past 12 months.

Funds for conducting this research are provided by the National Heart, Lung, and Blood Institute of the National Institutes of Health and the Department of Health and Human Services.

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.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 9 months.

The number of people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai is 58.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

The study has two components, 1) intervention or control visits, 2) research interviews. The intervention and control visits are those visits by the community health worker or COPD counselor either in your home or over the phone/video (Zoom or VSee). The research interviews are conducted by Research Coordinators (RC).

Research Interviews

During research interviews, we will be collecting information from you that helps us understand whether the Intervention makes a difference for people with COPD.

There will be three (3) research interviews over 9 months.

- **Interview #1 (baseline):** This interview will be at the location of your choosing (in the clinic, in your home, or over the phone).
    - You will be asked to complete survey questions about your health in general and your COPD and COPD medications.
    - You will be asked to complete a spirometry test, demonstrate your inhaler technique, and conduct a 6-minute walk test (6MWT). The 6MWT measures the distance you can walk for six minutes on a flat surface.
    - You may also receive an accelerometer so that we can measure your physical activity for 7 days after each research interview. An accelerometer is a small device worn on the waist to track how much physical activity you engage in.
    - We will also ask you to attach an electronic monitoring device to your inhalers for one month to track how often you use it. These electronic devices are attached to the medication and record how often you take your medication. These devices do not affect your ability to take your medication as prescribed from your healthcare provider. This data will be used for research purposes only but you can request the data to share with your healthcare provider.
- **Interview #2 (month 6):** We will ask similar questions and use the same assessments that are used for Interview #1.
- **Interview #3 (month 9):** We will ask similar questions and use the same assessments that are used for Interview #1.

The length of time for the research interview will vary for every participant. But you can expect it to take about 1 hour.

Group Assignment

This study is a randomized control trial. This means that if you agree to participate, the study treatment you get will be chosen by chance, like flipping a coin. Neither you nor the researchers will choose whether you get the Intervention or the Control. You will have an equal chance of getting the Intervention or the Control. The study procedures for each group were discussed in the Summary of this Research section above.

USE OF YOUR DATA

The researchers would like your permission to keep the data collected from you during this study for use in future research studies. Please tell us how we may use these data in future research studies.

(1) Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your information might be used, or to discuss possible participation in another research project? Please initial your choice:

Yes_____ No_____

(2) Will you allow the researchers to store your information and/or specimens to use in future research studies?

Yes_____ No_____ If no, please stop here. If yes, please continue to the next question.

(3) The researchers can keep your information and/or specimens stored in one of two different ways: one way will store your information and/or specimens in a way that it is linked to your identity (through the use of a code that can indicate the information came from you personally) and the other way will store your information and/or specimens anonymously (no one will know who the information is from). It will not be stored both ways, so you must choose one of these two options. Please note that if you choose to have your information and/or specimens stored anonymously, you will not be able to change your mind to ask for your information and/or specimens to be destroyed at a future date. How would you like your information and/or specimens stored? Please initial **ONE** choice:

I would like my information and/or specimens stored with a link to my identity_____
I would like my information and/or specimens stored anonymously _____

(4) Do you give the researchers permission to keep the information you provide us for this study indefinitely and use it for future studies that are **directly related** to the purpose of the current study? Please initial your choice:

Yes_____ No_____

(5) Do you give the researchers permission to keep the information indefinitely and 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_____

(5.1) From time to time researchers outside of medicine and related sciences would like to use this information. This might be in the field of anthropology, human origins, mapping human migration patterns etc. Do you give permission to use your information and/or specimens outside the fields of medicine and biological sciences? Please initial your choice:

Yes_____ No_____

(a) If the future research in a different area can be done without having to know that the information and/or specimens came from you personally, that will be done.
(b) If the future research in a different area requires that it is known specifically who the information and/or specimens came from, then one of the following will be done:
(i) If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your identifiable information or specimen is needed and what will be done with it. Your permission will be asked to use your information and/or specimens in that research project.
(ii) If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical, for example, because you have moved, your identifiable data and specimens may still be used. The Institutional Review Board (IRB) will be asked for permission to use the information and/or specimens linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the information and/or specimens will not be more than a minimal risk to you or your privacy. The Institutional Review Board (IRB) is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.

(6) Do you give permission to have portions of the specimens and/or information given **to other researchers,** including those at Mount Sinai, other academic institutions and for profit companies, for use in research within the limits you have chosen above? Please initial your choice:

Yes_____ No_____

(7) Do you give permission to have portions of the specimens and/or data **deposited in large public repositories, (explained below)** for use in research with the limits you may have chosen above? Please initial your choice:

Yes_____ No_____

Future Research Opportunities:

The researchers would like to ask your permission to keep your contact information to contact you for future research studies.

*(1) Do you give permission to have your contact information given to other researchers at Mount Sinai or other institutions for use in research **that is related to the purpose of this study**? Please initial your choice:*

*Yes*_____ No_____

*(2) Do you give permission to have your contact information given to other researchers at Mount Sinai or other institutions for use in research **that is not related to the purpose of this study**? Please initial your choice:*

*Yes*_____ No_____

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

YOUR 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:

- Participate in the activities that are assigned to you during randomization (based on chance like the flip of a coin)
- Participate in 3 research interviews
- Wear the accelerometer for 7 days after the research visit and return them to study personnel through the mail
- Attach the electronic device to COPD medication for one month after the research visit and return them to study personnel through the mail. These devices do not affect your ability to take your medication as prescribed from your health provider
- Contact your physician or pulmonologist if you have a significant change in your symptoms. This study should not replace your interactions with your primary care provider

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you for your time and effort to participate in *the research interviews. You will not be paid for intervention or control activities. This means that you will not be paid for visits with the community health worker, pharmacist, or* clinician*, or visits with the research coordinator to review the COPD educational booklet.*

For research interviews, you may receive up to $255 for participating in this study. We will pay you $65 after the completion of the each interview. If you complete all 3 interviews you will be paid a total of

$195. Up to an additional $20 will be given to subjects after every interview once they return the electronic monitoring device for the medication ($10) and an accelerometer ($10). You will be paid in cash or money order at the completion of each interview. *Payments will be for the research interviews only. We will not pay you for your visits with the CHW.*

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from 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 a better understanding of managing your COPD. If you participate in the intervention group you may feel better and have fewer COPD symptoms. Your benefits from participation may not continue after the research has ended. Results from this study could benefit others in the future by improving how we help people with COPD.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- Physical risks – You may feel lightheaded after performing the spirometry test. Possible risks for research subjects assigned to the intervention are tiredness and shortness of breath from the clinician's evaluation and exercises you do at home. Also, if you are prescribed an emergency pack medication and you use those medications to treat a COPD exacerbation, you could experience side effects including nausea or stomach pain. Contact your primary care provider and/or the pharmacist if you experience these effects.
- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- Legal risks (for example, being reported for child abuse) – The research team and CHW may visit you in your home and witness your everyday life. If a reportable offense, such as child, domestic, or elderly abuse is suspected they will be required to report it to the authorities.
- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.
- Risk of personal information sharing through background communication among phone applications. Certain mobile applications can communicate with each other through the device, potentially exposing personal information to unauthorized external entities. This is a common risk in using most mobile phone applications.

OTHER POSSIBLE 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, you could continue your usual care as prescribed by your physician.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator. 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 investigator for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator 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 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 study doctor, the sponsor or the institution 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 study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data 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 Principal Investigator at phone number 212-824-5765.

If you experience an emergency during your participation in this research, contact 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:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/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 you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be shared with others?</u>
As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail addresses, and medical records number. The researchers will also get information from your medical record within the Mount Sinai Health System and other institutions in contract to share medical records of shared patients.

During the study the researchers will gather information by:

- Taking relevant 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.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, 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 Principal Investigator.)

- Other collaborating research center(s) and their associated research/clinical staff who are working with the investigators on this project: Northwestern University and City Health Works because they are research partners on this study.
- 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: National Heart, Lung, and Blood Institute
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- Propeller Health, the developer of the Propeller Health sensor and associated platform. They will receive minimal protected health information during the study which may include patient name, email, telephone number, date of birth, mailing address , prescription information, and data collected through the sensors as part of the study. They will have

access to this information because they are responsible for collecting the data through the platform and providing technical support.

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research participants like you.

- Propeller Health company or designee will use the information collected to create a separate data set that does not include your name, email address or any information that can identify you attached to it. Anything that can identify you will be kept private.

Disclosure of identifiable information in the event of an issue with your Propeller Health device

- Propeller Health has a legal obligation to maintain records regarding complaints and incidents related to their device, which includes both the sensor and the application. In the event that you have a complaint or there is an incident related to the device, Propeller Health may collect identifiable information regarding the complaint or incident for their records. This information can include your name, contact information, device ID, and information related to the complaint or incident.

In almost all disclosures outside of Mount Sinai, 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 Principal Investigator 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.* We may publish the results of this research. However, we will keep your name and other identifying information confidential.

<u>For how long will Mount Sinai be able to use or disclose your protected health information?</u>
Your authorization for use of your protected health information for this specific study does not expire.

<u>Will you be able to access your records?</u>

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information 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?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the 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.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, 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, Mount Sinai 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 New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are 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 research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators 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.

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

_____	_____	_____
Signature of subject	Printed Name of Subject	Date

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date

WITNESS SECTION:
When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

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 subject, and that consent was freely given by the subject.

_____	_____	_____
Signature of Witness	Printed Name of Witness	Date