

VA Portland Health Care System (VAPORHCS) Informed Consent Form

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Subject Name: _____ Date: _____

Title of Study: ORCATECH Collaborative Aging (In Place) Research Using Technology (CART)

IRB Number: M4089, eIRB#17123

Principal Investigator: Lisa Silbert, MD

ICF Version Date: 02/22/2019

WHO SHOULD I CONTACT IF I HAVE QUESTIONS OR CONCERNS OR WISH TO OFFER INPUT?

About the research, call study investigator Dr. Lisa Silbert at (503) 494-6976.

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call Dr. Lisa Silbert at (503) 494-6976.

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VA Regional Counsel at (503) 412-4580.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. The purpose of this study is to create a nationwide home-based system for research that will determine how we can optimally enhance the health and wellbeing of older Veterans. This is to be accomplished by participants completing regularly scheduled assessments and questionnaires, as well as using simple existing technologies such as medication minding pill boxes and wristwatches that assess mobility and sleep to ideally detect early health and activity changes occurring in daily life. The long-term goal is to maintain health and independence with aging with a nationwide network of participants informing researchers as to how best achieve this goal.

The information collected as a part of this study, including information that can identify you, will be stored ("banked") in a repository located at Oregon Health & Science University. The repository may then release your information for use in future aging related research.

You have been invited to be in this research study because you are a Veteran 62 years or older, living alone or with a cohabitant, and are living independently or with minimal assistance, OR you are the cohabitant of a Veteran who is eligible to participate in the study.

WHO IS PAYING FOR THIS STUDY?

This study is being paid for by the Veterans Administration and the National Institutes of Health.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 200 people recruited through the Portland VA study site will participate in this research study.

Additionally, about 600 people will participate at 3 other sites across the United States, for a total enrollment of up to 800 people at all sites.

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Subject's Identification (I.D. Plate or complete below)

_____, _____, _____
LAST FIRST SSN (last 4 digits)

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HOW LONG WILL I BE IN THIS STUDY?

Your participation in this study will last for approximately 3 years unless you withdraw before the end of the study.

WHAT WILL HAPPEN DURING THIS STUDY?

There are two parts to this study: clinical assessments and in-home monitoring.

Clinical assessments

If you agree to participate in this research project, you will be asked to have a baseline study visit with research staff which will include the consent process, filling out demographic and health information, and completing a number of assessments with research staff. Each year, you will have a follow-up assessment visit and will update demographic and health information at that time. Please note that these assessments are being conducted as part of a research study and are not for use as part of your clinical care. All information will remain confidential, as stated in the CONFIDENTIALITY section. Further description of these assessments and the time required can be found below in the study visit table below.

At your baseline home visit, you will have your photograph taken. The photograph will be stored in the ORCATECH Management Console (OMC) with your information, available only to study staff to provide them a visual confirmation that when they go to visit a participant, they are speaking to the right person. In turn, you will be provided a document with contact information and photographs of study staff who may contact them during the course of the study.

During your visit, we may ask to record some of your responses to the tests. The voice recordings will be stored indefinitely in password-protected computers as part of the repository for this study. Your name or other protected information will be not used. Instead, we will identify you by assigning a unique identifier to your voice recordings.

In Home Monitoring

We will install in-home sensors to help us monitor your physical and computer activity patterns and how those patterns relate to changes in your medication and cognition. We will put this sensor system in your home to collect information about your computer use and activity throughout your home. The sensor system requires an Internet connection – typically via broadband service. In order to participate in this study, you will need to provide your own broadband service – typically \$40 – 60 per month. Your household will receive a monthly stipend of up to \$100 for the duration of the study to compensate you for your time and to offset the cost of

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Internet service.

To begin, the study staff will set up a time for the system to be installed in your home, which will take up to three hours depending on the size of your home. The sensor system will be taken out of your home at the end of this study or when you wish to stop taking part. This will take about 30 minutes and will be done at a time that is convenient for you.

In-home Assessment System Components:

Components required for study participation

- A small computer will be used to collect and send us the sensor information. This device will be placed in your home in a location that is out of sight.
- You will be asked to complete a weekly online behavior and health questionnaire that typically takes less than 5 minutes to complete. You may receive a phone call to follow-up on your responses if information you provide is not complete or appears inaccurate.
- Sensors will be placed on exit or entry doors to tell us when they are open or closed.
- Motion sensors will be placed in each room of your home, including your bedroom, bathroom, hallway, kitchen, and other living areas. These sensors do not record any sound or pictures, but simply tell us when a person passes in front of them.
- You will be asked to wear a watch-like device daily during the study. This device helps us understand your physical activity levels both in and out of the home.

Optional components

- You will be asked to weigh yourself on a scale daily which will communicate with our system.
- You will be asked to use a pillbox device for your medication. This device allows us to look at your medication taking habits.
- If you have a car that you drive that is a 1996 or newer model, we will install a sensor in the car that will track your driving habits during the duration of the study.
- You will be asked to have software installed on your computer which monitors your basic computer use. This software will be removed at the end of the study.
- You will be asked to have a sensor placed under your mattress (NEW device in 2019). This device will enhance and validate the sleep data which is already being collected by the watch-like device and the motion sensors. This device collects heart and breathing rates, heart rate variability, and movement activity (such as tossing and turning).

All sensors will be attached with removable picture hanging strips. There is a small risk that some paint will

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come off the wall when the sensors are removed. If there is damage, we will do our best to repair it.

Please note that the sensor system is *not* a security system. It will not detect break-ins, falls or emergencies and will not be able to notify anyone in the event of an emergency.

The system detects activity in your home and wirelessly sends the information to the research project staff. All data is kept strictly private (as described below in the CONFIDENTIALITY section). Data from the computer installed in your home will transfer securely to an OHSU research server. Data from your scale and car will transfer securely to the device manufacturer's server and will then be transferred to an OHSU research server.

During the project, you may be asked to allow research staff to come into to your home to test, replace or re-install parts of the sensor system. We will try to make as few visits as possible. If there is more than one person who lives in your home, each person will sign a consent form to participate in this study. At the end of the study, we will set up a time to remove the system.

In the future, your data may be given to researchers and the funder of this project for other research studies. The data will be labeled as described in the **CONFIDENTIALITY** section.

During this study you will be photographed at one of the initial visits only. We will use the photograph only for research purposes; it will be included as part of your entry in our research database. It will not be used for publicity purposes.

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CART Visits and Assessments						
	Baseline Visit	Platform Installation Visit	Month 12	Month 24	Month 36	Platform Removal
Consent & Authorization Forms	X					
Demographics Form	X					
CART SES & Employment Form	X		X	X	X	
Physical Health Assessments						
Physical Assessment Form	X		X	X	X	
Mobility Form	X		X	X	X	
Subject Health History	X		X	X	X	
Subject Medications	X		X	X	X	
Clinician Assessed Medical Conditions	X		X	X	X	
Modified Cumulative Illness Rating Scale (CIRS)	X		X	X	X	
OARS ADL/IADL	X		X	X	X	
Physical Activity Scale for the Elderly (PASE)	ONLINE		ONLINE	ONLINE	ONLINE	
Pittsburg Sleep Quality Index	ONLINE		ONLINE	ONLINE	ONLINE	
Habit Assessments						
CART Habits Form	X		X	X	X	
Cognitive & Behavioral Assessments						
CART Cognitive Status Form	X		X	X	X	
MoCA	X		X	X	X	
Craft Story 21 (Immediate)	X		X	X	X	
Benson Complex Figure Copy (Immediate)	X		X	X	X	
Number Span Forward (WAIS-R)	X		X	X	X	
Number Span Backward (WAIS-R)	X		X	X	X	
Category Fluency (Animals)	X		X	X	X	

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Category Fluency (Vegetables)	X		X	X	X	
Trail Making Test, Part A & B	X		X	X	X	
Craft Story 21 (Delayed)	X		X	X	X	
Benson Complex Figure Recall	X		X	X	X	
Multilingual Naming Test (MINT)	X		X	X	X	
Letter Fluency (F, L)	X		X	X	X	
Generalized Anxiety Disorder 7-item (GAD-7)	X		X	X	X	
UCLA Loneliness Scale	ONLINE		ONLINE	ONLINE	ONLINE	
Lubben Social Network Scale	ONLINE		ONLINE	ONLINE	ONLINE	
Geriatric Depression Scale (GDS)	X		X	X	X	
Care & Support Assessments						
Zarit Burden Interview (Couples only)	ONLINE		ONLINE	ONLINE	ONLINE	
Quality of Life						
RAND 36-Item Health Survey (SF-36)	ONLINE		ONLINE	ONLINE	ONLINE	
Technology Related Visits and Assessments						
ORCATECH Technology Use Survey	ONLINE		ONLINE	ONLINE	ONLINE	
CART Platform Installation		X				
Device Usability Evaluation			ONLINE	ONLINE	ONLINE	
CART Participant Experience Survey			ONLINE	ONLINE	ONLINE	
CART Platform Maintenance/Upgrades		As needed during the CART project				
CART Platform Removal						X
Online Weekly Questionnaire		Weekly for duration of CART project				
TIME PER VISIT	2-3 Hours	1-3 Hours	1-2 Hours	1-2 Hours	1-2 Hours	.5-1 Hour

All in-home assessment sessions will be audio recorded to allow for review of assessments and further analysis.

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Study staff may contact you by phone regarding responses to your weekly online questionnaire and may request access or (if you are enrolled in the VA system) access your medical record for more information about events referenced in your questionnaire responses.

WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?

There is a potential risk to anyone with a pacemaker who uses the scale provided by the study. The Nokia Body Cardio circulates a small electrical signal in your body to perform some of its measurements such as fat mass, which may interfere with a pacemaker or other medical device. If you have a pacemaker you are advised to wear shoes/socks while stepping on the scale. Study staff will also disable the functionality of the scale that can interfere with a pacemaker if you have one. If you get a pacemaker during the course of the study, please alert your study team so they can disable the functionality of the scale that can interfere with a pacemaker.

There is a minor risk that sensors installed in your home (described in more detail below) may fall from surfaces and potentially cause injury or damage. These sensors weigh less than 0.25 pounds and are about the size of a man's thumb. We will do our best to repair any damage caused by the sensors.

There is always a risk of a loss of confidentiality. All study personnel will receive training about HIPAA and the responsibilities that accompany the conduct of research. The repository housing data from this protocol (OHSU eIRB#17189) contains policy that defines procedures for protecting patient and subject confidentiality in compliance with OHSU and HIPAA guidelines, for accessing limited data sets, and for protecting the integrity of original work contributed to the database.

By storing or sending personal information on your computer there is some risk that it may be accessed by any with physical or remote access to your computer. If your computer is lost or stolen, the person in possession of the computer may have access to information you would choose to keep confidential. Because of this, you should always exercise caution in what information you put on the computer. The software that we install on your computer encrypts (or scrambles) the data it transmits so that it cannot be accessed by people other than those granted access by this document.

Information that identifies you will be used in this study and shared with the study sponsors, research staff, and non-VA researchers associated with the project. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. You are responsible for the physical security of the study equipment in your home. If someone not involved in this research removes the hub computer from your home, they would potentially be

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able to access the sensor data from your home.

Information that directly identifies you, or could be used to identify you will be banked for the purpose of use in future research. The repository team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft.

In this study, you will be asked questions about your quality of life at the yearly assessments. Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor.

The weekly health survey will ask you about your mood and health. These questions are part of the research study and are not meant to detect urgent medical needs. If you feel you need urgent medical attention during the course of this study, you should contact your primary care provider or call 911. If you are having thoughts of suicide, you should call the National Suicide Prevention Hotline and/or the Veterans Crisis Line, which will be provided on the weekly health survey. If the study team does become aware of a potentially urgent medical issue during the course of the study, we will refer you to your primary care provider and the National Suicide Prevention Hotline and/or the Veterans Crisis Line, if indicated.

WILL I BENEFIT BY PARTICIPATING?

Your household will receive up to \$100 for each month that you have the CART platform installed in your home for 7 or more days. This payment is to compensate you for your time and help defray the cost of the required broadband service. You may find may feel less isolated due to visits from study staff. There is otherwise no direct benefit associated with participation in this study, although older veterans living far from medical care may benefit from the information gained from this study in the future.

DO I HAVE TO PARTICIPATE IN THIS STUDY?

No. You may choose not to be in this study.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

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Identifiers related to you (i.e. information that can identify you) will be used in this research study and will include: name, geographical subdivision smaller than a State, date elements relating to you including your birthdate and dates associated with sensor data, telephone number, social security number, e-mail address, vehicle identifiers (from driving device if applicable), URLs, IP addresses, a photograph of you, and audio recordings from your assessment sessions. These identifiers may be used to obtain information about you and/or your health from VA records.

Information related to you will be shared with other researchers as part of this study and may include the following identifiers that may identify you or your family members: name, geographical subdivision smaller than a State, date elements relating to you including your birthdate and dates associated with sensor data, telephone number, e-mail address, vehicle identifiers (from driving device if applicable), URLs, IP addresses, and a photograph of you.

Your information will be shared with other researchers as part of this study. A code number will be assigned to your information. Personnel for this study and Qualtrics survey software will be authorized to link the code number to you. Other researchers who may receive your information will be given only the code number and will not be given any other information to link the code back to you.

All other parties, including employers, insurance companies, personal physicians and relatives, will be refused access to the information, unless you provide written permission or unless otherwise required by law.

Ownership of a copy of all study data (including name, geographical subdivision smaller than a State, date elements relating to you including your birthdate and dates associated with sensor data, telephone number, e-mail address, vehicle identifiers (from driving device if applicable), URLs, IP addresses, and a photograph of you) will be transferred to Oregon Health & Science University and will be the responsibility of Dr. Jeffrey Kaye, the overall principal investigator for the CART study.

Upon signing the study consent form, ownership of all future data will transfer to the overall CART study principal investigator, Dr. Jeffrey Kaye at OHSU and will be the responsibility of Dr. Jeffrey Kaye at OHSU.

By signing this informed consent, you give permission for the transfer of a copy of this information to the ORCATECH (Oregon Center for Aging & Technology) research servers at Oregon Health & Science University. Dr. Jeffrey Kaye at Oregon Health & Science University will be responsible for maintaining the security and confidentiality of the transferred data. VAPORHCS will continue to have ownership of your research data for this research study. All original research records, both hard copy and electronic, will be

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maintained at the VAPORHCS in accordance with current records retention requirements. Any information shared with Oregon Health & Science University may no longer be protected under federal law. Research records may be reviewed and/or copied by the sponsor.

Some study tests are completed in an encrypted database called REDCap. The REDCap database is a password protected and maintained by the Oregon Clinical & Translational Research Institute (OCTRI) at Oregon Health and Science University (OHSU). A user profile based on your study ID number will be created for you, which will not contain your name or other identifying information. The database will collect your responses to questions, but will not contain any identifying information about you. By signing this informed consent, you give permission for this data to be maintained by OCTRI, which will be responsible for maintaining the security and confidentiality of the transferred data.

Some study surveys are completed using cloud software called Qualtrics. Qualtrics is password protected. Your full name, study ID number and email address will be stored on the Qualtrics server, in order that you may be sent personalized links to the study surveys and to enable CART study staff to manage survey administration. The Qualtrics server will collect your responses to questions. By signing this informed consent, you give permission for this data to be stored on the Qualtrics servers and maintained by CART study staff, who will be responsible for maintaining the security and confidentiality of the transferred data.

At the baseline home visit, you will have your photograph taken on a study provided device (computer, tablet or cell phone). The photograph will be stored in the ORCATECH Management Console with your information, available only to study staff to provide them a visual confirmation that when they go to visit you, they are speaking to the right person. In turn, you will be provided a document with contact information and photographs of study staff who may contact them during the course of the study. During your assessment visits, we may ask to record some of your responses to the tests. The voice recordings will be stored indefinitely in password-protected computers as part of the repository for this study. Your name or other protected information will be not used. Instead, we will identify you by assigning a unique identifier to your voice recordings.

Your data may be disclosed to the sponsors of this study: the Department of Veteran's Affairs and the National Institutes of Health. Your data may be disclosed to others outside the VA who are involved in conducting or overseeing this research.

Information may be sent to the National Alzheimer's Coordinating Center (NACC) funded by the National Institute on Aging. The only piece of identifying information that will be shared is your age. Your identity will not be disclosed unless you give separate and specific consent for it.

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To help us protect your privacy, this project and the National Alzheimer's Coordinating Center – NACC have obtained Certificates of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Mandatory reporting of suspected child or elder abuse. Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

Possibility of Disclosure and Notice of Privacy Practices.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it may no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. If you do not have a copy of the notice, the research team will provide one to you. (Notice of Privacy Practices available online at http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=3048).

If you are a non-Veteran, we will provide you with the VA Notice of Privacy Practices and ask you to sign the acknowledgment (VA Form 10-0483) you received the document. This acknowledgement may be scanned into your medical record.

HOW LONG WILL YOU KEEP MY INFORMATION?

Your information will be stored indefinitely.

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WILL I BE ABLE TO SEE MY RESEARCH DATA?

During this research study, you will not be able to see the research data collected about you. After the study is complete and the study results are determined or published, you may request your health information. However, if we find information that is relevant to your health care, we will notify you and suggest that you discuss this information with your primary care provider or other trusted clinician.

WILL I BE TOLD ABOUT THE STUDY OR FUTURE RESEARCH RESULTS?

You will be able to request a copy of research publications that result from this study data.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

In order to participate in this study, you will need to provide your own broadband service – typically \$40 – 60 per month. Your household will receive a monthly stipend for the duration of the study to help offset the cost of Internet service (see below).

WILL I BE PAID FOR PARTICIPATING?

Your household will receive up to \$100 for each month that you have the CART platform installed in your home for 7 or more days. This payment is to compensate you for your time and help defray the cost of the required broadband service. You will receive EFT or cash voucher payment at the end of each month of your participation.

An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

WHAT WILL HAPPEN IF I AM HURT?

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, the VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures. Additional compensation, beyond paying for treatment, has not been set aside. The VA will also provide all necessary assistance in the event of any violation of confidentiality or privacy (for example, identity theft resulting from the loss of a social security number by anyone associated with this study). For eligible Veterans, compensation damages may be payable under 38 United States Code 1151. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with the provisions of the Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA Regional Counsel at (503) 412-4580. You

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have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

WHO SHOULD I CONTACT IF I AM INJURED DUE TO THE RESEARCH?

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact Dr. Lisa Silbert at (503) 494-6976. In the event of a life-threatening emergency, call 911 or go to the Emergency Department (ED).

WHAT ARE MY RIGHTS?

You may ask questions about research or about your rights as a subject. Dr. Lisa Silbert at (503) 494-6976 will answer any questions you may have about this research study. If you have any questions regarding your rights as a research subject, you may contact the VA Portland Health Care System Research Office at (503) 273-5125, or VA Regional Counsel at (503) 412-4580.

Participation is voluntary. Your participation in this research study is voluntary. The VA Authorization for Use and Release of Individually Identifiable Health Information (Collected) for VHA Research to use your protected health information is also voluntary. You may refuse to sign this consent form and the authorization. However, in order to participate in this study, you must sign this consent form and the authorization.

Dr. Lisa Silbert is a researcher on this study and may also be your health care provider. She and your other providers are interested in both the clinical welfare of their patients who participate in this study and in the conduct of this study overall. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another provider who is in no way associated with this study. You are not under any obligation to participate in any research study offered by your health care provider.

What if I decide not to participate? You do not have to join this or any other research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or if you drop out of the study at any time, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

CAN I DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?

You may withdraw from this study at any time. This will not affect your rights as a VHA patient or your eligibility for medical care and benefits for which you are otherwise eligible with this institution or with the VHA.

Do NOT Change Anything below this line, including bottom margin.

VAPORHCS Research Service Template Date: 03/13/2017

VA Portland Health Care System (VAPORHCS) Informed Consent Form

Page 14 of 16

Subject Name: _____ Date: _____

Title of Study: ORCATECH Collaborative Aging (In Place) Research Using Technology (CART)

IRB Number: M4089, eIRB#17123

Principal Investigator: Lisa Silbert, MD

ICF Version Date: 02/22/2019

To withdraw, you must write to Dr. Lisa Silbert at Mailstop P-3-Neuro, 3710 SW U.S. Veterans Hospital Road, Portland, OR 97239 or ask a member of the research team to give you a form to withdraw your consent and authorization. If you withdraw your consent and authorization, you may not be able to continue to participate in the study.

If you choose to withdraw from the research study we will arrange a time to uninstall the CART Platform from your home and may ask you to complete any assessments you would have completed as part of the study within the next 2 months (for example, if you withdraw after 10 months of participation, we may ask you to complete the 12 month assessments).

If you do withdraw, we will not look at your medical record for purposes of the research anymore and will not collect any more information about you. However, we will keep and use the data that we already collected before you withdrew your consent. The data collected before your withdrawal may not be removed or destroyed.

Can someone else stop me from being in the study?

Your participation may be terminated by the investigator if there is any reason to believe you cannot or will not comply with all study requirements.

WILL I BE TOLD IF THERE IS NEW INFORMATION THAT MIGHT CAUSE ME TO WANT TO QUIT THIS STUDY?

We will give you any new information during the course of this research study that might change the way you feel about being in the study.

CAN I WITHDRAW MY PERMISSION TO USE MY INFORMATION?

To withdraw your consent for use of your information, you must write to Dr. Lisa Silbert at Mailstop P-3-Neuro, 3710 SW U.S. Veterans Hospital Road, Portland, OR 97239 or ask a member of the research team to give you a form to withdraw your consent and authorization. If you withdraw your consent and authorization, you may not be able to continue to participate in the study. You will still receive all the medical care and benefits for which you are otherwise eligible. This will not affect your rights as a VHA patient.

Do NOT Change Anything below this line, including bottom margin.

VAPORHCS Research Service Template Date: 03/13/2017

VA Portland Health Care System (VAPORHCS) Informed Consent Form

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Subject Name: _____ Date: _____

Title of Study: ORCATECH Collaborative Aging (In Place) Research Using Technology (CART)

IRB Number: M4089, eIRB#17123

Principal Investigator: Lisa Silbert, MD

ICF Version Date: 02/22/2019

Signature

Dr. Lisa Silbert or another authorized member of the research team has explained the study and the banking of my information to me and answered all of my questions. I have been told of the risks and/or discomforts and possible benefits of the study and banking.

I have been told I do not have to take part in this study, including banking, and refusal will involve no penalty or loss of VHA or other benefits to which I am entitled.

In case there are problems or questions, I have been told I can call Dr. Lisa Silbert at (503) 494-6976 from 9 am to 5 pm, Monday through Friday. If any medical problems occur in connection with this study, the VA will provide emergency care.

My signature below indicates that I have read, or had read to me, all of the above information about the study and banking of my information, and that my rights as a research subject have been explained to me. I authorize the use of my information as described in this form.

In the future, if I decide that I no longer wish to participate in this research study, I agree that my information, which were already collected, may continue to be used for this research and as a part of the repository.

I voluntarily consent to participate in this study and allow the information from this study to be stored in a repository and used for future research, as described in this form. I have been told that I will receive a copy of this consent form.

Printed Name of Subject

Signature of Subject

Date

Time

Do NOT Change Anything below this line, including bottom margin.

VAPORHCS Research Service Template Date: 03/13/2017

VA Portland Health Care System (VAPORHCS) Informed Consent Form

Page 16 of 16

Subject Name: _____ Date: _____

Title of Study: ORCATECH Collaborative Aging (In Place) Research Using Technology (CART)

IRB Number: M4089, eIRB#17123

Principal Investigator: Lisa Silbert, MD

ICF Version Date: 02/22/2019

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

Time

Do NOT Change Anything below this line, including bottom margin.

VAPORHCS Research Service Template Date: 03/13/2017