University of Southern California
Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy
1540 Alcazar Street, CHP 133, Los Angeles, CA 90089

INFORMED CONSENT FOR RESEARCH

Study Title: Toward development of a comprehensive, in-home, active seating system to lessen sedentariness and improve health and wellness in older adults.

Multiple Principal Investigators: Stacey Schepens Niemiec, PhD, OTR/L, DipACLM (USC) & Roger Leib, AIA, ACHA (Activ Sitting, Inc.)

Department: Mrs. T.H. Chan Division of Occupational Science and Occupational Therapy

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

PURPOSE

The purpose of this study is to develop a seating system called FitSitt to improve older adults' movement during sitting activities across the day. We hope to learn if this device is acceptable to older adults and useful in safely improving their overall patterns of physical activity as they go about their daily seated routines. You are invited to participate because you are aged 65 or older; live in the local Los Angeles area; and self-report an ability to safely do light-intensity physical activity. About 15 people will take part in this stage of the study. This research is being funded by the National Institute on Aging.

PROCEDURES

Study activities will take about two weeks to complete. Researchers will visit you in your home at the beginning and end of the study. If you decide to take part, this is what will happen.

- Fill out questionnaires online at the beginning and end of the study
- Wear an activity monitor for up to 10 full days and a keep a log of wearing it
- Wear a health monitor on your wrist for up to 7 full days during the FitSitt trial period
- Research staff will bring the FitSitt system to your home for you to use up to 7 days
- At a visit that will take about 2 hours, staff will show you how to use the system and educate you about sedentary activity
- After the 3 to 7-day trial of FitSitt, you will be interviewed about your experience with the system, either online or in-person. This will take about 1.5 hours.
- Staff will pick up the FitSitt at the end of your trial with the system

RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include:

Surveys/Interviews: Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don't want to answer.

Activity Monitoring: Wearing an activity-tracking device, including the tape required to adhere it, may irritate your skin. You may request a soft foam wrap that we can place under the monitor before fitting you with the monitor to protect your skin. The activity monitor has a battery in it similar to a Fitbit that will be touching your skin. You may feel embarrassed placing the monitor on your thigh that requires exposure of the upper part of your leg when you put it on.

Health Monitor Device: Wearing a health monitor device on your wrist may irritate your skin. We will keep your skin dry and clean to reduce this risk and loosen the strap as needed. This device has a small infrared and circuitry board in it that will be in close contact with your skin.

Seated Exercise Device: We encourage you to use a seated exercise device at a light speed and resistance appropriate for you. The recommended use will mimic light intensity walking. Risks are similar to using any kind of fitness device unsupervised. They include:

- *Muscle strain/soreness*: There is a risk of muscle strain or soreness in your lower body from doing more activity than you normally do. To minimize soreness, we will recommend you pedal on the chair no more than 1 hour in total across the whole day.

- *Joint pain/swelling*: Use of the device requires a pedaling motion and may temporarily increase pain in your lower joints that you may have from conditions like arthritis. The severity of risk might depend on your individual ability and medical history; however, you were asked to be in this study because you stated you were healthy enough to do light physical activity. Please consult with a healthcare provider before changing your physical activity routine.

- *Tripping/loss of balance*: You may trip over the pedals of the device or lose your balance if you do not brace yourself properly when moving from sit to stand and back.

Breach of Confidentiality: There is a small risk that people who are not connected with this study will learn your identity or your personal information. Any data we collect through FitSitt, identifiable only by a code, will be transferred to a secure system for storage to protect confidentiality.

BENEFITS

There are no direct benefits to you from taking part in this study. However, your participation in this study may help us learn about the best design of an active seating system to help older people live healthier lives. Eventually, this device could be available to the public.

PRIVACY / CONFIDENTIALITY

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who are required to review this information. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

Interviews with you will be audio recorded. During recorded sessions, we will refer to you using a false name to protect your identity. If personally identifying information is recorded, the research team will delete or modify this information so it is not intelligible in the recording. The people who work on the study will see the notes and typed discussions of recorded sessions. Recordings will be stored on a secure data server at the University of Southern California until the transcription and analysis processes are completed. Once complete and the standard period for storing information from the study has passed, the audio files will be destroyed.

Any data we collect through the FitSitt system, such as how much you pedal or how frequently you sit in the chair, will be identifiable only by a code. Your personally identifying information will not be linked to these data. All data collected will be transferred to a secure system for storage to protect your privacy and confidentiality.

Phone calls and text-based communications from the research team will be conducted through Google Voice, a landline, or a cell phone. We will not include any personally identifying information in communications with you to protect your privacy.

The University of Southern California's Institutional Review Board (IRB) and Human Subject's Protections Program (HSPP) may review your records. Organizations that may also inspect and copy your information include the National Institute on Aging (NIA) /National Institutes of Health (NIH).

Your data collected as part of this research will be used or distributed for future research studies without your additional informed consent. Any information that identifies you (such as your name) will be removed from the data before being shared with others or used in future research studies.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If your contact information was obtained from the Healthy Minds Research Volunteer Registry, some of your personally identifying information may be stored on the HIPAA compliant, secure web application called Ripple Science, designed for storing and managing research participants' information. Study researchers may additionally track other information related to the study, such as recruitment, appointments, and completed tasks using this application. Please note, however, results from or performance on study tasks will never be stored in Ripple Science. For Healthy Minds participants, please note that personally identifying information you provide during this study may be added or updated to your existing record in the USC Healthy Minds Research Volunteer Registry. Examples of such information include English fluency and your contact information.

ALTERNATIVES

An alternative would be to not participate in this study.

PAYMENTS / COMPENSATION

There is no cost to you for taking part in this study. You will receive up to a total of $145.00 in a check mailed at the end of your participation in the study. If you do not complete all study activities, your total payment will be prorated, based on each study activity you did complete, as follows:

In-home Testing Stage (up to $145 total at end of study)
• $10 complete questionnaires at the beginning of the study
• $20 wear an activity and health monitor for up to 10 days
• $20 complete a 2-hour in-home orientation to *FitSitt*
• $50 utilize a *FitSitt* prototype in home for 3 to 7 days
• $10 complete questionnaires at the end of the study
• $20 complete a follow-up interview
• $15 return the loaned activity and health monitor

Payments for research participation are considered taxable income and participants may be required to pay taxes on this income. If participants are paid $600 or more in total within a calendar year for participation in one or more research studies, the University will report this as income to the IRS and participants may receive an Internal Revenue Service (IRS) Form 1099. This does not include any payments you receive to pay you back for expenses like parking fees.

Possible Commercial Products
If a commercial product is developed from this research project, the commercial product will be owned by Activ Sitting, Inc. You will not profit financially from such a product.

COST
There is no cost to you for taking part in this study.

POTENTIAL CONFLICT OF INTEREST
Mr. Roger Leib, a Multiple Principal Investigator on the study team and CEO of Activ Sitting, Inc. has a financial interest in this study. His company is the manufacturer of the seating system that you will be using in this study. Mr. Leib is one inventor of the seating system and he may benefit financially if it is marketed. Stacey Schepens Niemiec, Associate Professor of Research at USC and Multiple Principal Investigator on the study has no affiliations to Activ Sitting or conflict of interest. Tuan Hoag, CTO of Senseer Health, faculty of USC, and consulting on the study is providing support to build and analyze the sensors of the seating system, but does not have affiliation to Activ Sitting and therefore does not have a conflict of interest.

VOLUNTARY PARTICIPATION
It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to.

If withdrawal must be gradual for safety reasons, the investigator will tell you. The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

PARTICIPANT TERMINATION
You may be removed from this study without your consent for any of the following reasons: you do not follow the study investigator's instructions, at the discretion of the study investigator or the sponsor, your condition gets worse, or the sponsor closes the study. If this happens, the study investigator will discuss other options with you.

CONTACT INFORMATION
If you have questions, concerns, complaints, or think the research has hurt you, talk to the study investigator Stacey Schepens Niemiec at 323-442-2069 or email her at schepens@usc.edu.

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed

Person Obtaining Consent

I have personally explained the research to the participant and/or the participant's legally authorized representative using non-technical language. I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed

**If a study procedure is done on the same day the informed consent is signed, the time and date are required.*