



University of California, San Diego
Consent to Act as a Research Participant

Research Study: Measuring what you do and where you go during the day

Jacqueline Kerr, PhD, in the Dept of Family and Preventive Medicine, is conducting this research study to better assess human movement in normal settings. This study is funded by the National Cancer Institute (NCI) of the National Institutes of Health.

You are being asked to participate in a research study that lasts for 7 days. Before you decide to participate, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

The purpose of this study is to understand the types of movements you make across the day including sitting, walking, driving, etc. There will be approximately 210 people from the San Diego area in this study.

To be eligible for this study you have to meet the following criteria:

a) provide written consent to complete study protocols; b) willing to complete to visits to the UCSD campus; c) willingness to wear multiple sensor devices on 7 days for 12 hours per day; d) willingness to wear wrist accelerometer on 7 days for 24 hours per day; e) complete 2 surveys; f) willingness to have height and weight measured; g) be physically and cognitively able to walk unassisted, h) able to read and understand study materials in English.

Description of the Study

If you agree to be in this study, the following will happen to you:

You will attend two meetings at UCSD that will last approximately 60 minutes each.

Meeting 1 – 60 minutes

You will meet with research staff for an initial evaluation for approximately 60 minutes. In this meeting, we will take your height and weight, and explain how to wear the study sensors. These are described in more detail below.

A. Survey: You will complete a 30-minute survey including questions about your lifestyle, health, and daily activities.

B. Wear Sensors: You will be asked to wear four small sensors for 7 days. Two of the sensors are worn on a belt around your waist. One is worn around your neck. You will wear these three devices for waking hours only. The watch size device you wear on your wrist is worn 24 hours, including while you are sleeping. The sensors tell us about your movements throughout the day and when you are sleeping, where you go, and what you see along the way.

- a. 2 small motion-detection devices (called ‘accelerometers’), 1 worn at the waist and 1 on the wrist, which measure motion. These devices are about the size of a wrist watch.
- b. a location detecting device called a Global Positioning System (GPS). This is a device that records where you travel and is worn on a belt around your waist. The GPS device is about the size of a small cell phone.
- c. a small device worn on a lanyard around your neck. The SenseCam includes a small camera, and sensors that measure light, temperature and movement. The camera takes photographs at regular intervals which helps researchers understand the context in which your activity is occurring (e.g., busy streets, presence of bike lanes, sitting at a desk, etc.) To protect your privacy, you can turn the camera off at any time. Special procedures to protect your privacy when using the SenseCam are described in the section on “Confidentiality” below.

C. Sleep log: You will be asked to complete a sleep log during the 7 days that you wear the sensors.

Meeting 2 - 60 minutes:

A. Sensors: You will bring back the Sensors and be given time to review the images in private and delete any images that you don’t want us to see.

B. Survey: You will complete a 30-minute survey including questions about your lifestyle, health, and daily activities. If you are under 13, we will ask your mom or dad to complete the survey on your behalf. The survey will ask questions about what it’s been like to wear the devices around your waist and the camera around your neck. Everything you tell us is strictly private.

What is Experimental in this Study

Wearing the motion-detection device, the GPS and the SenseCam during your daily life and completing the surveys is experimental.

Risks

The risks involved in this study are minimal. Participation in this study may involve some physical discomfort to you from wearing the devices. You may also experience discomfort or a sense of loss of privacy as a result of revealing your location and daily activities or answering survey questions. You may feel discomfort wearing the SenseCam because it takes images of what you are doing throughout the day. You are free to remove the camera at any stage, and there is a privacy button you can press to stop the camera recording for 7 minutes. Also you will be able to review the images and delete any you do not wish researchers to see. You can discontinue participation at any time. There may also be concern for privacy related to divulging personal information or the loss of confidentiality if device data are



accessed by an unauthorized person. Your data will be stored appropriately in locked cabinets and on a secure computer server that is password protected in order to minimize the risk of loss of confidentiality. There may also be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Benefits

You will not receive any benefit from participating in this study. Benefits of this study are principally to the scientific community to help understand the accuracy of sensors for measuring human behavior. There could be an increased awareness of your physical activity level and pattern and/or surrounding environment.

Payment for Participation

In compensation for your time and travel, you will receive \$25 at each of 2 visits for travel to the offices. You will also receive a \$50 incentive after wearing the devices for 7 days and returning them to us. You will be paid via a preprinted check that can be cashed at any bank. No form of ID is required to cash the check.

Care If Harmed

If you are injured as a result of participation in this research, the University of California will provide any medical care needed to treat those injuries. The University of California will not provide any other form of compensation if you are injured. You may call the UCSD Human Research Protections Program office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject, or to report research-related problems.

Questions about the Study

Dr Jacqueline Kerr or _____, of the research team has explained this study to you and answered your questions. If you have other questions or research related problems, you may reach Dr. Kerr at (858) 534-9305.

Voluntary Nature of Participation

Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time. Your decision of whether or not to participate will not jeopardize your future relations with the University of California San Diego or benefits to which you are otherwise entitled.

You may be withdrawn from the study if the Principal Investigator believes that it is in your best interest. You may also be withdrawn from the study if you do not follow the instructions provided by the study personnel.

Alternatives to Participation

The alternative to participating in this research project is to choose not to participate.

Confidentiality

Research records will be kept confidential to the extent provided by law. All responses and data collected from the devices will be kept confidential within the research team, and no material that could personally identify you will be used in any reports or publications from this study. Your data will be stored appropriately in locked cabinets and on a secure



computer server in order to minimize the risk of loss of confidentiality. All information collected for this research that is stored on our secure computer will be identified by subject ID number only. Results of this study may be reported in scientific journals, meeting, and news media. None of these reports will use your name or use data that can point to any person who took part in the study. Strict security measures will be taken to insure that none of these procedures results in release of any information you provide us. You give your permission to the researchers to store your data for use in analyses that have not yet been specifically planned at this time. Your data will be kept for ten years. Researchers conducting these studies will not contact you for any additional information.

Several aspects of the procedure are designed to safeguard your rights and privacy as a participant. The SenseCam is equipped with two methods to deactivate the camera at any time, should you want your activities to remain private (i.e., certain places, times, or situations). The two methods are:

- 1) The SenseCam has an ON/OFF button for complete deactivation (off) or reactivation (on).
- 2) The SenseCam has a “DO NOT DISTURB” button which will put the camera into “DO NOT DISTURB” mode. In this mode, the camera will remain on but absolutely no images will be captured. The SenseCam will remain deactivated for 7 minutes, and will alert you with a beep 15 seconds before it reactivates. You may press the “DO NOT DISTURB” button again to reset the “DO NOT DISTURB” mode to last for another 7 minutes. You may also reactivate the SenseCam from “DO NOT DISTURB” mode at any time by pressing the manual shutter button.

In addition, should you want any images to be deleted that were inadvertently captured (e.g. during a time when you would have preferred for the SenseCam to be deactivated but forgot to deactivate it), you will be able to note the time period in a small notepad which we will provide to you. As soon as you return to the measurement office you will be given the opportunity to review and delete any images you wish prior to them being seen by research staff.

Furthermore, several aspects of the procedure are designed to ensure the rights and privacy of other people who may appear in the images captured by SenseCam. These include:

- 1) A reference card will be provided for you to carry around while wearing the device. This includes:
 - a. a prepared statement to read to anyone with questions or concerns about the SenseCam; “I am participating in an experiment on physical activity and the environment. This is a digital camera that automatically captures low-resolution still images throughout the day, which will later be used to describe my behavior and environment. It does not record audio or full-motion video. Any images captured will not be made public in any fashion and will only be seen by the researchers. If you would prefer, I can turn off or temporarily deactivate the camera, and/or make a note and have the images just taken deleted without anyone seeing them. I can also provide contact information for the researchers.”
 - b. a list of places and situation in which we ask you to deactivate the SenseCam



i. Place/Situations:

1. Any restroom
2. Any changing room, locker room, etc.
3. Doctor's office
4. ATM or bank
5. Wherever/Whenever you would prefer for images not to be captured
6. Wherever/Whenever anyone requests deactivating

c. Contact information for the investigators (email, address and phone number)

- 2) A small notepad in which to note periods of time for image that you want deleted.

Procedures for Termination

If you decide to withdraw from this study, you will be required to notify a member of the research team and return the devices if they are still in your possession.

Sponsor Inspection

The sponsor of this study, the National Institutes of Health, National Cancer Institute, will have access to general research data but will not have the right to access patient medical records or clinical charts.

Research records may be reviewed by the UCSD Institutional Review Board.

Agreement

You have received a copy of this consent document to keep and the "*Experimental Subjects Bill of Rights*." You agree to participate.

Signature

Date

Witness

Date

