

Wearable Camera Research Protocol and Consent Content

Additions due to Apple Watch breach

Research Plan:

Risks

Should include capture of non-study individuals (bystanders) engaged in private activity, which is not necessarily illegal

Risk that the participant may be potentially liable for the images captured??

Risk Management Plan (Protocol #140510: Approved 11/5/2015)

This study involves no experimental procedures or behavioral manipulations, only device-based behavioral monitoring of a participant's usual daily routines. All study procedures and participant involvement involve minimal risk. Data monitoring procedures are therefore commensurate with the risks. Because of the minimal risk, the data and safety monitoring (DSM) plan for this study focuses on close monitoring by the Principal Investigator (PI) with prompt reporting of serious adverse events (including disclosure events) to the university Institutional Review Board (IRB) and the NIH if applicable. Data for monitoring and safety will come from self-reports from participants as well as bloodwork. The project coordinator will be responsible for assembling the data and producing these reports, as well as assuring that all relevant parties obtain copies of these reports. The reports will include information about subject accrual (adherence to protocol regarding demographics, inclusion/exclusion) and adverse event rates.

Risk of embarrassment: Participants will be told that they have the option to turn off the SenseCam when they are doing an activity that causes embarrassment. The research focuses on daily routine activities or other generally acceptable activities that are commonly not any cause for embarrassment or secrecy. Participants will also be told that they can refuse to answer any survey question during their campus visits.

Physical, psychological, social, or economic risk as a result of a breach in confidentiality will be managed by 1) using devices that cannot be downloaded by participants, only authorized members of the research team. For example, the SenseCam has no viewfinder or image display and images cannot be seen or downloaded without the use of specialized, password-protected software; and 2) having a strict data security protocol in place. Specifically, we keep informed consent statements and participant data in separate locked files cabinets so that individuals are not easily connected to the study results. All sensor data will be stored on a firewall and password-protected project server at the University of California, San Diego. All data will be kept in locked cabinets at the study office, accessible only by investigators and project staff. Participants will also be told about the confidentiality procedures and that they have the right to refuse to answer questions or to terminate their participation in the study at any time without prejudice. Finally, participant data will not be sold or exchanged with anyone and data sharing as per NIH requirements will be performed within strict protocol-driven procedural guidelines. The PI will assure that all human protections standards are met.

It will be explained to participants both verbally and in the written consent form, that they will have several options to restrict image capture from the SenseCam:

1. The SenseCam is equipped with an ON/OFF switch for complete deactivation and reactivation
2. The SenseCam is also equipped with a “DO NOT DISTURB” mode which completely halts image capture for 4 minutes with an audio alert 15 seconds before image capture resumes.
3. Participants will also be provided with small notepads to record time intervals for which images will be deleted without the investigators review of the data
4. Participants will review the collected images during the Visit #2 and delete any images they wish.

In order to protect the privacy of other individuals, participants will be provided a reference card explaining the SenseCam to other people who may incidentally appear in the low-resolution images and will be instructed to deactivate the SenseCam at the request of other people, and in locations where a person may expect privacy such as in restrooms, changing or locker rooms, doctor’s offices, and at ATMs or in banks.

The images on the SenseCam are scrambled so can only be downloaded by the researcher with specialized software. Participants cannot download or post images. In order to protect their privacy and the privacy of others who may appear in the images, the images will not be released to participants under any circumstances. Participants are also encouraged to remove the SenseCam in any encounter or situation where it might attract unwanted attention.

We believe that application for an NIH Certificate of Confidentiality is not warranted for this study because (a) recorded behaviors are considered non-sensitive in nature; and (b) the SenseCam data collects images of participant’s environment and not of the participant themselves (the participant cannot be identified in the images).

However, a disclosure protocol defines a set of procedures that will be enacted following the discovery of events (from the SenseCam images or direct observation) that are potentially illegal or detrimental to the welfare of the participant or others’ during the research process. This includes activities such physical assault or battery, shop-lifting, accidents or injury. Specifically,

- i. disclosure protocols and reporting procedures will be discussed with participants at the beginning of the study;
- ii. evidence of a potential disclosure event be obtained from the SenseCam data or direct observation;
- iii. further discussion of the event will take place with the participant.
- iv. the Principal Investigator will consider the question of disclosure in relation to the seriousness of each event, whilst considering the participant’s right to confidentiality and anonymity;
- v. if disclosure is considered a necessary course of action, the Principal Investigator will make contact with the most appropriate person (e.g., parent, school principal, police);

- vi. the participant will be kept fully informed of any disclosure;
- vii. the Principal Investigator will document any disclosure.

Consent:

Risk that the participant may be potentially liable for the images captured??

Include this statement:

These protocols are in place to protect you and protect anyone else who may be captured in images by the SenseCam you are wearing.

1. Device description: Clear description and definition of MISST method or device(s) including a description of the method/device, where and when the device will be worn, and what data is being collected. Language should be used to state that MISST devices are not significant risk devices and should not be considered medical devices. If PHI is being collected/processed in real time that should be noted as well. For example:

The wearable camera incorporates a digital camera and multiple sensors including a thermometer to detect ambient temperature, a passive infra-red sensor to detect the presence of a person in front of the wearer, and a light sensor, to help it detect when to take a picture. It is worn on a lanyard suspended around the neck and captures first person point-of-view images. The automatic image capture generates up to 3,000 images per day approximately every 20 seconds. The device is charged nightly. Data on the device is encrypted so that images may not be downloaded by study subjects (*research plan description*).

The following is an example of language for the SenseCam in an adult consent form:

Description of Device: a small camera worn on a lanyard around your neck called a SenseCam. The SenseCam includes a small outward facing 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. You will wear this camera for 7 days. You will be given the SenseCam at your first measurement visit. (*Protocol #140510*)

2. Risks: Physical (e.g. injury or discomfort from devices), psychological (e.g. embarrassment, concern for being “tracked”/location being known if using GPS), economic/social (e.g. possibility of being teased by wearing the devices or being socially excluded), and legal risks (e.g. research finding out that the research participant engaged in an illegal activity) and loss of confidentiality.

Language about mandatory reporting must be in the consent form if the study will have access to or collection of information that Federal, State, and/or local laws/regulations requires or may require to be reported. For more information about mandatory reporting, please review the application instructions, section 16: <http://irb.ucsd.edu/BioMedapplication2013Instructions.pdf> and the sample adult consent form: http://irb.ucsd.edu/Biomedical_forms.shtml

Additionally, researchers have developed a “disclosure” protocol for imaging data that outlines procedures to be adopted following the discovery of events either “illegal or detrimental to the participant or others recorded during the research process”. This must be read and understood by all researchers and staff engaged in research with person worn cameras.

In addition to addressing plans to reduce the identified risks and the procedures for maintaining confidentiality, risk management procedures should include:

- options for research subjects to stop collecting data (e.g. ability to take off or turn off device, privacy buttons on the SenseCam, list of places and situations to turn off a device)
- if applicable, whether the data collected (e.g. location from GPS) is collected in real time and how the researchers will process it (e.g. GPS data is not processed in real time, so researchers will not know a research subject's location in real time)
- if applicable, options for research subjects to delete data that was collected (e.g. research participant has the option to view images from a SenseCam and delete any images prior to them being seen by research staff)
- if applicable, options for research subjects to respond/address concerns from bystanders (e.g. ability to turn off or take off the device, reference card that research subjects can keep with them *"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,"*)

1. The following is an example of language for the SenseCam in an adult consent form related to risks::

2. The risks involved in this study are minimal. Participation in this study may involve some physical discomfort to you from wearing the devices or bruising if you were to fall while wearing the SenseCam. You may feel embarrassment or anxiety from wearing the SenseCam because it takes images of what you are doing throughout the day or from being teased or excluded because you are wearing the device. 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 4 minutes. You will be able to review the images and delete any you do not wish researchers to see at your second measurement visit. Images captured by the SenseCam device that show instances of assault and abusive conduct, including abuse or neglect of children, elderly or dependent adults will be reported along with contact information. There may also be legal risks if the images from the SenseCam show illegal activities (e.g. shoplifting, bodily harm). Some people involved in genetic studies have felt anxious about the possibility of carrying an altered gene that they could possibly pass down to their children. If as a result of participation in this study, we obtain information that could significantly affect your health and well-being; we will attempt to inform you of the existence of this information. (*Protocol #140510*)

3. Confidentiality

4. The following is an example of language for the SenseCam in an adult consent form related to confidentiality:

Confidentiality: In order to protect your privacy and the privacy of others who may appear in the images from the SenseCam, the images will not be released to you under any circumstances.

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 4 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 4 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. During your second measurement visit, 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.

(Protocol #140510)

5.

Data storage and analysis: If data may be stored for future use, the research plan and consent form must reflect that. The consent form must include the Moores Clause (<http://irb.ucsd.edu/BioMedapplication2013Instructions.pdf>, section 12). For example, “

“Your data may also be used in studies by other researchers from UCSD and other Universities. Dr. Kerr will be responsible for deciding how your data will be used. If you withdraw or are removed from the study, your data will still be used in these analyses by Dr. Kerr. Dr. Kerr, her associates, or her successors in these studies will keep your data and the information derived from it for an indefinite period. You consent to such uses.” (protocol #140510)

4.

5. Data sharing: If data may be shared/accessed outside of the key personnel listed on the research plan, the data sharing plan must be described.

All PIs and key personnel engaged in MISST research must have current CITI training certificates that are kept on file by the Project Manager (http://irb.ucsd.edu/CITI_UCSD_Training.pdf). Additionally, researchers and staff who are involved with viewing, coding or analyzing SenseCam images must read the Ethical Framework for SenseCam research and sign declaration form that they have understood the procedures (Appendix).

These questions include:

I confirm I have read and understood the Ethical Framework for SenseCam research	
I confirm I have completed the Ethical Training appropriate to my institution	
I undertake to protect the privacy and confidentiality of all participants and their SenseCam data	
I understand that I must not disclose the content of any images to anyone outside of the research team	
I understand that I cannot make any copies of any images or post copies to any internet sites (Facebook, Twitter, etc)	
I understand that I must not send images over any unsecured internet connection (i.e. e-mail)	

I understand that data will be stored on a secure server (e.g. behind institutional firewall) and should never be stored on unprotected, mobile devices. (A password encryption will be provided)	
I must not share images with any third-party vendor that was not pre-defined in the approved study protocol	
I understand that any images used in presentations, papers or reports must be approved by the Study Principal Investigator before use	
I understand that I must report images that depict illegal activities (including but not limited to abuse or violence) to the Study Principal Investigator	

