



COLLEGE OF ENGINEERING
COMPUTER SCIENCE DIVISION
449 SODA HALL, #1776
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Consent to Participate in Research: Intelligent Personalized Monitoring of Ambulatory Human Biosignals

My name is Reza Naima. I am a PhD student at UC Berkeley, working in the Berkeley Institute of Design under supervision of my advisor, Dr. John Canny. We are conducting a research project to investigate a wearable device for continuously collecting human vital signs data during normal daily activities. We hope eventually to demonstrate a device that could be worn comfortably for extended periods that would monitor a person's vital signs and warn of early signs of any developing health issue. However, in the current research, we are only testing the device on healthy subjects to see if it can reliably collect useful data and whether that data can be analyzed in a meaningful way. We are *not* performing any medical diagnostics on anyone in the current research. We are asking you to participate by wearing the device and allowing the device to record your vital signs as you wear it through your daily routines up to 24 hours, as described below. You may refuse to participate or discontinue participation in the research without penalty or loss of benefits to which you are otherwise entitled.

Who can be a participant. You can be a participant if you are between the ages of 18-75, generally healthy, are able to competently wear the device, are fit to perform the activities required, and do *not* have one of these particular conditions:

1. Mitral valve prolapse or heart murmur
2. Active keratitis, conjunctivitis or "pink eye"
3. Aneurysm
4. History of retinal detachment
5. Implanted pacemaker or cardioverter defibrillator
6. Allergic response to adhesives, synthetic and natural fibers, or plastics.

Beyond the above listed conditions, we will be performing a fifteen to twenty minute long interview. During the interview, we will be familiarizing you with the materials and the study, what we expect you to do during the study, and verifying that you understand all the aforementioned conditions and that none of them apply to you. You will have multiple opportunities during the interview to ask questions about any aspect of the study. At any point during the interview, if you do not feel comfortable with wearing the device, or do not understand or feel incapable of performing the tasks required of you, then you will be excluded from the study. Beyond the interview, if we notice any potential problems, such as an allergic response, then we also exclude you from the study.

The device. Our device is about the size of a cell phone, and has electrical leads that will be stuck to your skin at several locations, like a band-aid. The locations will be selected from these, though it may not be all of them: (a) around your chest, (b) just below your rib cage, (c) the base of your neck, (d) your back, and/or (e) just above or below your collar bone. You will wear these connections under all clothing. You will be provided with a wearable holster for the device for your waist or around your neck like a necklace. The device runs on a battery equivalent to a household 9v battery, so it cannot give you any kind of dangerous shock. The device records your biosignals while you wear it, including your heart rate and output, your blood oxygen level, your respiration, your temperature, your motions, and the impulses to some of your muscles. It does not record anything else; for example, it does *not* record your voice or your location.

What you will be asked to do. If you choose to participate, we will first measure your weight and height, and ask your age. We will fit the device onto you at our office. We will ask you to perform a sequence involving the following activities, which will take about 35-40 minutes:

1. Lying down and sitting (you may read or listen to music)
2. Standing for up to 10 minutes
3. Walking around our office.
4. Walking up and down stairs up to 5 minutes
5. Holding your breath for as long as you are comfortable holding it.
6. Performing a "Valsalva maneuver" which means forcibly trying to exhale while keeping your windpipe, or mouth and nose, closed.



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After we have you do these activities in our office, we will ask you to continue wearing the device for up to 24 hours, including while asleep, and then return the device to us. We will also ask you to keep a log of your activities and times, so that we have some idea of what activity you were doing at each point in the recorded data (such as “driving”, “watching TV”, “sleeping”, “eating”, “jogging” and so on). You are free to remove the device and electrical leads at any time, and cease participating. You should remove the device and leads before you shower, go swimming or otherwise get wet.

When you return the device, we will ask you about your experience wearing the device, and ask you to stay while we extract the data. Your total time commitment will be approximately 24 hours, though for most of this you can go about your daily routine. Your time commitment spent with us will be about 1 hour.

Risks of participating. There are minimal possible risks associated with this study. As with any research that deals with daily life, there is the potential for breaches of confidentiality or embarrassment from having investigators detail household activities. We will do as much as is possible to mitigate these risks, and you may always choose not to answer any of the questions that we ask you, or request that we destroy your recorded data.

There is small risk that you may find the electrical leads irritating to the skin. If the locations where the leads are attached become itchy or painful, remove the leads and please let us know. Since this kind of irritation may be an allergy, you may want to apply an antihistamine ointment, or take over-the-counter antihistamine, which we can provide to you on request.

There is also a small risk that the device or electrical leads may distract you, the same way a cell phone or MP3 player or headset might. Please use caution while driving.

Confidentiality of your data. We will ask for your contact information in order to contact you with possible follow up questions regarding your activities while wearing the device, if questions arise from the data. We will maintain confidentially a list that connects your contact information with your dataset during the period of our research, but we will never share that list with any third party. Furthermore, we will generally make the data anonymous, and use the data in our analyses on an anonymous basis. If we publicly present, share or publish your data, it will be completely anonymous and without any details that could be used to identify you in any way. At the end of our research on the data, we will delete your contact information, unless you allow us to keep it so that we may involve you in subsequent trials. Your data will be handled as confidentially as possible

Participation is voluntary. Your participation in this research is voluntary. You are free to refuse to take part. You may stop taking part in the study at any time without penalty or loss of benefits to which you are otherwise entitled, and any data collected will be destroyed if you so request. There are no direct benefits to you for participating in this study. However, if the device proves reliable and useful, the study may benefit society by improving the quality and timing of healthcare.

Compensation. You will be compensated by payment according to the table below. There are no costs to you for participating in the study.

Length of Collected Data	Compensation
Over 30 Minutes	\$15
Over 3 Hours	\$20
Over 7 Hours	\$45
Over 14 Hours	\$60
Over 20 Hours	\$80
24 Hours	\$100

If you have any questions about the research, you may telephone me: (415) 713-3753 or contact me by e-mail: reza@reza.net. If you agree to take part in the research, please sign the form below. Please keep the other copy of this agreement for your future reference.

If you have any question regarding your treatment or rights as a participant in this research project, please contact the University of California at Berkeley's Committee for Protection of Human Subjects at (510) 642-7461.

I have read this consent form and I agree to take part in this research.

Signature: _____

Date: _____

FOR USE ***AFTER*** COLLECTION OF DATA:

I agree to let you keep my contact information, so you can invite me to participate in future studies of this device.

Signature: _____

Date: _____