CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

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Project Number: 2009010

Project Title: Customized Health Alerts and Consumer-Centered Interfaces Using In-Home and Wearable Sensors

INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

You are being asked to participate in a research study. This research is being conducted by Dr. Marjorie Skubic and the Eldertech Research Team at the University of Missouri to explore technologies that could potentially be useful in the future for people with cognitive or mobility impairments, but for this study we are asking senior citizens with no cognitive impairment to participate. Please take your time to make your decision and discuss it with your family and friends.

When you are invited to participate in research, you have the right to be informed about the study procedures so that you can decide whether you want to consent to participation. This form may contain words that you do not know. Please ask the researcher to explain any words or information that you do not understand.

You have the right to know what you will be asked to do so that you can decide whether or not to be in the study. Your participation is voluntary. You do not have to be in the study if you do not want to. You may refuse to be in the study and nothing will happen. If you do not want to continue to be in the study, you may stop at any time without penalty or loss of benefits to which you are otherwise entitled.

This research is funded by The National Institutes of Health.

The Principal Investigator, Marjorie Skubic, and her collaborators have financial interests in the technology being used in this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to explore the potential of technology interventions that can support senior citizens at home. We will refine a health alert system by developing new algorithms using data from in-home sensors and an electronic health record (EHR), that provide alerts of very early changes in health status and that are customized to the individual consumer. A consumer-appropriate interface will also be developed to help consumers better manage their own health, and we will explore their opinions on how the system could be used. In the future, such technology could be employed for people with functional or

cognitive impairments. At this point we want to explore this study with the general senior population to explore its usefulness. This research is being done because we aim to develop an integrated monitoring system that reliably captures data about older adults and their environment in a noninvasive manner and balances the needs of health safety and privacy.

HOW MANY PEOPLE WILL BE IN THE STUDY?

About 60 people total will take part in this study, who are residents of Tiger Place, Bedford Walk, Bethel Ridge Estates I & II, and Gentry Estates.

WHAT AM I BEING ASKED TO DO?

If you take part in this study, you will have the following tests and procedures:

A so-called In-Home Monitoring System (IMS) will be installed in your home. Such a system consists of a set of wireless infrared proximity sensors to detect motion that can be used to infer specific activities based on the position of the sensor. Other sensors include a bed sensor that senses the presence of a person on the bed, restlessness, and pulse and respiration rates, and a gait monitor that senses falls as well as normal or abnormal gait. You will be given an Amazon Echo Show so that you may access health data being collected easily and without needing a computer. This data is accessible by opening the "Health Assistant" skill on the Echo Show. You will be trained on how to use this device and how to obtain your health information. You will also be given the option of using a wearable fitness sensor which is battery operated. Motion sensors are also battery-operated. The bed and gait sensors have wired power connections similar to any other appliance. All use wireless data transmission. These sensors are being tested as monitoring devices for your safety and well-being. The sensors will be installed away from easy access so that no safety hazards are introduced.

A member of the research team will install the sensors in your home and will test and maintain the equipment at scheduled times when you are present (likely once a month). The research team member might ask you to walk around the house and observe to ensure that the equipment is functioning properly. This observation serves as the validity check for the equipment.

About every three months, you will be asked to participate in interviews to provide feedback about the technology system. A member of the research team will show you the system interface to get your input about what you seemed to like most or disliked, and will ask you to fill out a questionnaire about your experience. These interviews will last approximately 20 minutes.

In the event that a health alert is generated by the sensor system, a study staff member may call you by telephone or visit you in order to follow up on the health alert. You will also be given an opportunity to use the web-based interface at other times, via a secure login, according to your convenience, if you so desire.

If you choose to use the wearable wrist sensor, you will receive initial training and follow-up training on how to use this sensor, how to maintain it and keep it charged, and how to see the data it collects via an

online data interface. These sensors will be returned to the research team at the end of the study (you will not get to keep the wearable wrist sensor).

The research team will also collect standard subject data, including age, sex, marital status, weight, height, medical diagnoses (including all chronic illnesses) and medications; these data are collected because these factors may affect subjects' physical function. We will collect dates and reasons for all primary care and specialty office visits, ER visits, hospitalizations, nursing home stays, and falls with and without injuries; length of stay for hospitalizations and nursing home stays. In the study, we will investigate correlations among sensor data and health status.

All sensor data and health data will be de-identified and stored with a code number.

HOW LONG WILL I BE IN THE STUDY?

Our plans call for an 18-month study. The investigator may decide to take you off this study if funding is stopped or new information becomes available to change the study.

You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your relationship with the employees of your housing facility. The In-Home Monitoring System will be removed when you withdraw from the study.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

Study participants may benefit from having the health care research staff examining their sensor data displayed on the interface as alerted to do so by the in-home sensor system. It is likely that viewing the interface of sensor data will help the health care research staff to detect subtle changes that may be early indicators of illness or functional decline.

Through their participation, study participants will gain a more nuanced understanding of potential technologies available to assist them with monitoring their own functional performance and health status and that of their elderly relatives. Maintaining physical function is of primary concern for elders who are motivated to be as independent as possible, as long as possible.

WHAT ARE THE RISKS OF BEING IN THE STUDY?

There is minimal risk involved with your participation in this study. The sensors provide data that are not linked to your identity. The data are stored in a secure server accessible only to the research team and only for the purposes of the research. The research team will not be accessing any personal record. Study participants will have access to their own sensor data if they so choose (only their own sensor data); also, study participants may designate specific family members to have access if they so choose. Access to specific family members will be given if and only if the study participant approves. All access will be done via secure logins to control access. There is a risk of loss of confidentiality during the collection of interview data, when you will be speaking with a study staff member about your experience living with the sensor system. To minimize the risk of loss of confidentiality due to someone overhearing this

conversation, interviews will be conducted privately in your home or in another private space reserved for interviews.

There is no shock hazard associated with the sensors. The sensor system uses commercial equipment that conforms to the applicable standards; furthermore, equipment will be placed away from easy access.

If at any point during the study you are worried about the impact of your participation on yourself or the risks that the research team has described to you, notify the investigator Dr. Skubic immediately. Dr. Skubic's telephone number is (573) 882-7766.

WHAT ARE THE COSTS OF BEING IN THE STUDY?

There is no cost to you to you for participating in this study. You will not be charged for any of the technology that is part of this research study.

WHAT OTHER OPTIONS ARE THERE?

You have the option of not participating in this study, and will not be penalized for your decision.

CONFIDENTIALITY

The data collected from the sensors will provide information about motion and walking around the home and will only be used to test the effectiveness of the technology. Additional data include the presence of a person on the bed, bed restlessness, pulse and respiration rates in bed, and a gait monitor that senses falls as well as normal or abnormal gait. The data will be stored on a secure server, identified by code number only, accessible only to the research team and only for the purposes of this research study. Study participants will have access to their own data only, if they so choose. Family members will have access only if study participants approve. A privacy policy is required by Amazon for use of the Health Assistant skill on the Amazon Echo Show. This privacy policy may be viewed at https://concert.missouri.edu/policy.

Other information produced by this study (such as questionnaire responses, interview results, standard subject data, and health status data) will be stored on a secure server and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law.

The results of this study may be published in a book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

We will keep the information we collect from you for this study to use in future research/to share with other investigators to use in future studies without asking for your consent again. Information that could identify you will be removed from your research data so no one will know that it belongs to you.

In addition, if photographs, audiotapes or videotapes were taken during the study that could identify you, then you must give special written permission for their use. In that case, you will be given the opportunity to view or listen, as applicable, to the photographs, audiotapes or videotapes before you give your permission for their use if you so request.

WILL I BE COMPENSATED FOR PARTICIPATING IN THE STUDY?

You will receive no payment for taking part in this study. All sensors and durable study materials will be returned to the research team at the end of the study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Participation in this study is voluntary. You do not have to participate in this study. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future relationship with housing staff. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after she has explained the reasons for doing so.

You will be informed of any significant new findings discovered during the course of this study that might influence your welfare, or willingness to continue participation in this study.

WHOM DO I CONTACT IF I HAVE QUESTIONS, CONCERNS, OR COMPLAINTS?

You may ask more questions about the study at any time. For questions about the study or a research related injury, contact Dr. Marjorie Skubic at (573) 882-7766.

A copy of this consent form will be given to you to keep.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Campus Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-9585 or umcresearchcirb@missouri.edu.

If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing muresearchrpa@missouri.edu.

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Approval Date: February 27, 2020

You may ask more questions about the study at any time. For questions about the study or a research related injury, contact Dr. Marjorie Skubic at (573) 882-7766.

A copy of this Informed Consent form will be given to you before you participate in the research.

SIGNATURES

I have read this consent form and my questions have been answered. My signature below means that I do want to be in the study. I know that I can remove myself from the study at any time without any problems.

Subject	Date
Witness (if required)*	Date

**The presence and signature of an impartial witness is required during the entire informed consent discussion if the subject or subject's legally authorized representative is unable to read.*

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