PFI: BIC Affordable Mobile Assistive Robots for Elderly Care (Informed Consent Form)

NCT #02807506

AUGUST 24, 2017

University of Pennsylvania

Penn Medicine Rittenhouse
Department of Physical Medicine & Rehabilitation

Informed Consent and HIPAA Authorization Form

Name of Study Volunteer: _____

Protocol Title: PFI: BIC Affordable and Mobile Assistive Robots for Elderly Care

Principal Investigators:
Mark Yim, PhD
Tessa Lau, PhD
Michelle J. Johnson, PhD
Pamela Cacchione, PhD, APRN, GNP, BC
Contact Person:
Michelle J. Johnson PhD
1800 Lombard Street, Philadelphia, PA, 19146
Office: (215) 893 – 2665
Lab: (215) 893 – 2695

Why am I being asked to volunteer?

You are being invited to participate in a research study. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. *You have been invited to participate in this study because you are a Living Independently For Elders member and/or participating in the LIFE-affiliated retirement community or a Council of Elders member at LIFE.*

Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will provide you with this consent form to read. You may also decide to discuss it with your family, friends, or primary care provider. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to develop a new affordable robot with the participation of LIFE members and clinicians being part of the development process. Our ultimate goal is to build a low-cost robot platform that will focus on the simple, but key, repetitive, datadriven tasks that robots are known to do well. Rather than attempt to create a robot helper that mimics humans, we aim to free human caregivers from the time-consuming tasks that robots can easily accomplish thereby allowing humans to focus on tasks that humans do best (i.e. human contact).

.

How long will I be in the study?

Your participation in this part of the study may last for the duration of one interaction with the robot prototype (approximately½ hours) or for the duration of the study (approximately 2 years). If participating in the bean bag toss game, the duration of your participation may last up to 1 and ½ hours. *It is important to note that as features are added to the robot, you will be asked to sign a separate consent form each year.*

How many other people will be in this study?

You will be one of approximately 130 participants in this research study.

What am I being asked to do?

Your participation in this study may include the following steps:

1) You will be asked to fill out a short demographic survey. This survey includes questions pertaining to race, age, gender, etc., as well as your familiarity with technology.

2) You may take part in one or more user study consisting of key activities such as ***walking/exercising*** with a robot for up to 15 minutes a day, participating in a ***hydration*** task, and/or ***or playing a bean bag toss game***. If participating in the bean bag toss game, you will be asked to toss a bean bag with the goal of getting it into a hole. You will be asked to retrieve the bean bags from a high shelf and retrieve the bean bags from the ground after throwing. The game will be repeated 4 times. The first time with no assistance, the second time with assistance from the research team, and the third and fourth times with assistance from the robot. Your input will be solicited to help the research development team assess these activities that were previously ranked by a cohort of your peers as key tasks they would most like a robot to help them throughout the day. Additionally, your input will help us evaluate robot usability, usefulness, design, etc.

3) During a typical interaction a member of the research team will take notes on your interaction with the robot.

4) After a typical interaction with the robot you will be asked to complete a short post-encounter survey. Questions will include issues surrounding perception, utility, usefulness and will solicit any feedback you may have at the time. .

What are the possible risks or discomforts?

The risks associated with participation in either part of this study include:

x Frustration in being unable to understand the robot. x Frustration in being unable to complete a tasks (i.e. walking with the robot). x Falling while walking with the robot.

x Discomfort or embarrassment due to actions by the robot. Efforts will be made to ensure privacy in communication of sensitive reminders.

x Pain or muscle bruising in the event you bump into the robot or the robot gripper interacts with your hand when passing an object

x A possible loss of confidentiality as the research team cannot guarantee that what is said in the focus group will not be repeated outside of the session.

There may be some unknown or unanticipated discomforts or risks in addition to those specified above. Every precaution will be taken to assure your personal safety and to minimize discomforts. If you are experiencing discomfort you should inform a member of the research team immediately.

Any new findings discovered during the course of this project which may affect your willingness to continue participation will be provided to you.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to receive any major benefits from being in this research study. However, the information obtained from this study may be useful scientifically and may prove helpful to other members of society who find themselves in similar situations in the future.

What other choices do I have if I do not participate?

You may choose not to participate in the research study.

Will I be paid for being in this study?

USD 5 will be given to you for participating in a walking task or water task session with the robot.
USD 10 will be given to you for participating in the bean bag toss session with the robot.
USD 25 will be given to you for participation in a focus group or with a user study of the robot involving more than 3 sessions with the robot.

Will I have to pay for anything?

As a participant in this study, you or your insurance company will not be responsible for the costs of any study related activities such procedures required for the study. Insurance companies or other third party companies will not be billed for research purposes.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. Your participation in this study may also be stopped at any time by the Principal Investigator without your consent because:

x The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

x You have not followed study instructions. x The study's Principal Investigator has decided to stop the study.

<u>If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.</u>

What information about me may be collected, used or shared with others?

Information in the medical record, results of physical examinations, medical history, lab tests, or protected health information such as name, address, date of birth, audio, video or photographic images, and telephone and email, may be collected as part of this research study. If you are participating in a focus group, a digital audio recorder will be used for the entirety of the session. These audio recordings will then be uploaded (shared) with a company that specializes in medical transcription.

The research team will use and share your private medical information only for this study; however, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

x do the research x oversee the research

x to see if the research was done right.

Who can use and share my information? How will my personal information be protected?

The study investigators will store your private medical information in a safe place. Only people with permission will be able to see or use it. This is required by federal and state privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA). These laws protect your private medical information if they also have details that could reveal your identity such as birthdates, initials, addresses, and social security numbers can identify you. The law also protects information that may also identify your family, your housemates, or your employer.

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an authorization. By signing this form, you authorize the use and sharing of the following information for this research:

1. Your medical records and information we collect from you about your medical historyand your experience at LIFE and living at Kearsley.
2. Clinical and research data collected and observations made during your participation inthe research.

By signing this form, you authorize the following persons and organizations to receive your protected health information for purposes related to this research: members of the research team from LIFE, the school of engineering, the school of medicine, the school of nursing and Savioke, Inc. In addition, the federal government sponsor of this project, the National

Science Foundation, the appropriate offices of Living Independently for Elders, Good Shepherd Penn Partners, and UPENN's Institutional Review Board, which are responsible for ensuring your welfare and rights as a research participant, may review and or photocopy study records which may, if they feel it necessary, identify you as a participant.

If information obtained in this study is published, it will not be identifiable as your results unless you give specific permission. Good Shepherd Penn Partners and partnering entity will comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. A copy of the notice will be provided to you.

Who, outside of the LIFE, might receive my information?

Members of research team who are employed by other departments at the University of Pennsylvania. These include the school of engineering, the school of medicine, the school of nursing and the industry partner, Savioke, Inc. In addition, the federal government sponsor of this project, the National Science Foundation, the appropriate offices of Living Independently for Elders, Good Shepherd Penn Partners, and UPENN's Institutional Review Board.

Once your personal health information is disclosed to others outside the LIFE, it may no longer be covered by federal privacy protection regulations.

The Principal Investigators or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the LIFE and University of Pennsylvania use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

x You have given written authorization x The University of Pennsylvania's Institutional Review Board grants permission x As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 8982614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

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

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Signature Consent (Please Print)	Date