UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

If you are the legally authorized representative for the subject, as you read the information in this Consent Form, you should put yourself in the subject's place to decide whether or not to allow us to collect research information about the subject and to allow the subject to take part in this study. Therefore, for the rest of this form, the word "you" refers to the subject (adult participant).

If you are an adult participant reading this form, the word "you" refers to you.

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Accurate WiFi-Based Localizations of Dementia Patients for Caregiver Support.

3. Who do you call if you have questions about this research study?

Principal Investigator: Dr. Glenn E Smith: 352-273-6556-

Other research staff:

Priscilla A. Amofa Sr. (Sub-Investigator): 352-294-8674

Brittany DeFeis (Sub-Investigator): 352-294-8674

Shellie-Ann Levy (Sub-Investigator): 352-273-5928
Andrea Mejia (Sub-Investigator): 352-294-8674

Gelan Ying (Sub-Investigator): 352-294-8674

4. Who is paying for this research study?

The sponsor of this study is the National Institute of Health: National Institute on Aging through ASTER Labs, a technology and research laboratory in Shoreview, MN.

5. Why is this research study being done?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research, how long will you be involved?

The goal of this study is to fully evaluate the efficacy of the Activlink system by offering localization and wandering status of a dementia patient to improve caregiver quality of life. In particular, the study aims to:

- Reduce the direct emotional and economic burden of continuous patient oversight.
- Allow the caregiver remote localization.
- Provide highly accurate localization and real-time alerts of high risk movements during wandering or disorientation.
- Provide a localization device that is discreet, non-invasive, and that requires less effort from the patient.
- Give caregivers greater peace of mind and flexibility in their daily lives.

You are being asked to take part in this research study because you were diagnosed with mild to moderate dementia, or your partner, family member, or patient received this diagnosis. The study will include individuals diagnosed with mild and moderate dementia, and their family caregivers.

It will take approximately 6 months to complete this research study.

b) What is involved with your participation, and what are the procedures to be followed in the research?

For the persons with mild and moderate dementia, you will complete a cognitive screening. Additionally, you will wear a provided insole inserted into your own pair of shoes, and consent to be monitored. Data from the insole will not be labeled with direct identifiers such as your name. You will be randomly assigned to either have and wear the insole or not have the technology applied for a period of three months, followed by three months of the opposite condition.

For the caregivers, you will be asked to complete:

- Questionnaires related to your caregiver activities, caregiver burden, and quality of life. These will be mailed on a weekly basis throughout the six month span of the study.

c) What are the likely risks or discomforts to you?

This study focuses on the utility of a technology that tracks the location of a person with dementia while at home or in an assisted living facility. There are two primary risks associated with the study. The first is a loss of privacy for the person with dementia that the technology will track throughout the home. The second risk could be a false sense of security for the caregiver about the whereabouts of the patient. For example, if the insole is not operating correctly or is not worn, the caregiver may believe the person with dementia is in a safe location when they are not.

d) What are the likely benefits to you or to others from the research?

The expected benefits for participants are the feeling one might experience knowing they are helping to advance an aid that may potentially reduce the burden of caregivers. Utilization of the *Activlink* insole and mobile application will provide caregivers of persons with dementia with greater opportunities to continue with their daily activities with reduced concern.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

The alternative to participating in this study is to not participate.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

No additions to or deviations from normal clinical care will be present, and no clinical services will be provided through the study.

7. What will be done only because you are in this research study?

There will be additional tests and procedures as part of this research study in which you will be asked to participate.

For the persons with mild and moderate dementia, you will complete a cognitive screening. Additionally, you will wear a provided insole inserted into your own pair of shoes, and consent to be monitored. Data from the insole will not be labeled with direct identifiers such as your name. You will be randomly assigned to either have and wear the insole or not have the technology applied for a period of three months, followed by three months of the opposite condition.

For the caregivers, you will be asked to complete:

- Questionnaires related to your caregiver activities, caregiver burden, and quality of life. You will be asked to complete this two times a month \ throughout the six month span of the study.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

It will take approximately 6 months to complete this research study.

9. How many people are expected to take part in this research study?

204 individuals, both patients and caregivers, are expected to be enrolled to take part in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

This study focuses on the utility of a technology that tracks the location of a person with dementia. There are two primary risks associated with the study. The first is a loss of privacy for the person with dementia. The technology will track the patient throughout their homeor assisted living facility. . The second risk could be a false sense of security for the caregiver about the whereabouts of the patient. For example, if the insole is not operating correctly or is not worn, the caregiver may believe the person with dementia is in a safe location when they are not.

Other possible risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

11a. What are the potential benefits to you for taking part in this research study?

The expected benefits for participants are the feeling one might experience knowing they are helping to advance an aid that may potentially reduce the burden of caregivers. Utilization of the *Activlink* insole and mobile application will provide caregivers of persons with dementia with greater opportunities to continue with their daily activities with reduced concern.

11b. How could others possibly benefit from this study?

In achieving the study's aims, people diagnosed with dementia and their caregivers, can benefit by improving safety and quality of life through using future iterations of the *Activlink* insole.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

The alternative to participating in this study is to not participate.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from the study, information about you will no longer be collected but data that has already been collected before your withdrawal may be used in data analysis. However, you can request in writing to have all your information destroyed entirely.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- If it is in your best interest.
- If you don't follow the study procedures.
- If you are no longer eligible to participate in this study at any point.
- If the study is stopped.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

No. The sponsor will pay for or provide all required services and activities at no cost to you.

15. Will you be paid for taking part in this study?

Yes, you will be provided monetary compensation for your participation in the study. Specifically, patients and their family caregivers will be paid $125 dollars each to reimburse them for their time and effort for participation.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to ***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator.

16. What if you are injured because of the study?

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Name, telephone number, email address, confirmation of dementia diagnosis, questionnaire responses

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Information from the insoles will not be linked with an individual person, and data will be sent without any direct identifiers for all study purposes.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- We may use your PHI to determine your eligibility for the study, or to evaluate the outcomes on caregiver burden, activities, and quality of life.
- No personal data will be connected to or associated with the data from the insole.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- The study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- The University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization | Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self / Care Partner. By signing this form, you voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Adult Consenting & Authorizing for Self | Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-21 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____

Consent & Authorization Signature of Parent/Legal Representative | Date

_____ _____

Print: Name of Legal Representative | Print: Relationship to Participant:

_____

Print: Name of Subject:

Participants Who Cannot Consent But Can Read and/or Understand about the Study. Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, you both need to sign. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part

_____ _____

Assent Signature of Participant Date

ADDENDUM TO INFORMED CONSENT FOR AUTHORIZED REPRESENTATIVE

Study Title:	Study Number:

In the event that I _____, should become incapacitated (no longer able to make decisions for myself) during the course of this study, the person named below will act as my authorized representative to make decisions on my behalf, regarding continued participation in this research study.

Please list an authorized representative, if you were unable to make decisions for yourself.

Contact Name:		Relationship:	
Address:	City:	State:	ZIP:
Home Phone:	Alt. Phone:	Email:	

In an effort to help your authorized representative comply with your wishes, we are requesting your views about continued participation in this study should you become incapacitated (no longer able to make decisions for yourself). Please select one:

	1. I would like to fulfil my study participation as indicated in the informed consent.
	2. I would like my authorized representative as identified above to withdraw me from this study.
	3. I will let my authorized representative make this decision in my best interest.

Participants Signature:	Date:
Witness Signature:	Date:
Witness Printed Name:	