Sample Application for Small Business Funding

Through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, NIA aims to help small businesses develop effective treatments and interventions for healthy aging. NIH small business funding is competitive, and resubmissions are a common and important part of the award process.

Find more NIA sample applications and information about SBIR/STTR funding:
https://www.nia.nih.gov/research/sbir/nia-small-business-sample-applications

PI: **Sobol, Adam**	Title: CareBand: Wearable Technology for People with Dementia	
Received: 09/05/2018	FOA: PAS18-187 Clinical Trial:Optional	Council: 01/2019
Competition ID: FORMS-E	FOA Title: Advancing Research on Alzheimer's Disease (AD) and Alzheimer's-Disease-Related Dementias (ADRD) (R43/R44 Clinical Trial Optional)	
1 R43 AG063685-01	Dual:	Accession Number: 4210000
IPF: 10048406	Organization: CAREBAND, INC.	
Former Number:	Department:	
IRG/SRG: ZRG1 RPHB-Y (13)B	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: [redacted]	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: Early Stage Investigator:
Senior/Key Personnel:	*Organization:*	*Role Category:*
Adam Sobol	CAREBAND, INC.	PD/PI
Ellen Kaehr M.D.	Indiana Univesrity	Consultant
Daniel Bateman M.D.	Indiana University	Consultant
Todd Sobol M.D.	Optum Complex Care Management	Consultant

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION

Organizational DUNS*: [redacted]

Legal Name*: CAREBAND, INC.
Department:
Division:
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]

Person to be contacted on matters involving this application

Prefix: First Name*: Adam Middle Name: Last Name*: Sobol Suffix:

Position/Title: [redacted]
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: Email: [redacted]

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 813027282

7. TYPE OF APPLICANT* R: Small Business

Other (Specify):
Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
CareBand: Wearable Technology for People with Dementia

12. PROPOSED PROJECT

Start Date* Ending Date*
04/01/2019 08/31/2019

13. CONGRESSIONAL DISTRICTS OF APPLICANT
IL-007

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: First Name*: Adam Middle Name: Last Name*: Sobol Suffix:
Position/Title: CEO
Organization Name*: CAREBAND, INC.
Department:
Division:
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: USA: UNITED STATES
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: Email*: [redacted]

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested* [redacted]
b. Total Non-Federal Funds* [redacted]
c. Total Federal & Non-Federal Funds* [redacted]
d. Estimated Program Income* [redacted]

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ○ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
DATE:
b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR
○ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: Adam Middle Name: Last Name*: Sobol Suffix:
Position/Title*: Founder & CEO
Organization Name*: Careband
Department:
Division:
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: Email*: [redacted]

Signature of Authorized Representative*
Adam Sobol

Date Signed*
09/05/2018

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT File Name:

PHS 398 Cover Page Supplement

OMB Number: 0925-0001

Expiration Date: 03/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ○ Yes ● No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?

○ Yes ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)

PHS 398 Cover Page Supplement

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ○ Yes ● No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

❑ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents: ○ Yes ○ No

If the answer is "Yes" then please answer the following:

*Previously Reported: ○ Yes ○ No

5. Change of Investigator/Change of Institution Section

❑ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:

Middle Name:

*Last Name:

Suffix:

❑ Change of Grantee Institution

*Name of former institution:

Tracking Number: GRANT12704560 Funding Opportunity Number: PAS-18-187 . Received Date: 2018-09-05T11:45:40.000-04:00

Abstract

An estimated 5.5 million Americans age 65 and older are living with Alzheimer's disease (AD) and as the population ages, this number is expected to rise to 13.8 million by 2050. Agitation is one of the most common and distressing neuropsychiatric symptoms of Alzheimer's disease and related dementias (ADRD) for patients in the ambulatory and long-term care (LTC) settings. Agitation contributes to increased healthcare costs, greater caregiver distress and worse quality of life. A significant challenge in the management of agitation is obtaining real-time objective data on symptom patterns. Symptom rating scales are time consuming and frequently underutilized by LTC staff. Such subjective differences in symptom reporting makes measurement of treatment response or non-response quite difficult. Clinicians, LTC staff and caregivers need a more cost effective, simple way to objectively measure agitation. While efforts have been made to capture this data using wireless sensors, none to date have been made commercially available. CareBand, an Illinois-based small business, is developing an end-to-end wearable technology and real-time data platform for people living with ADRD. Preliminary studies have demonstrated CareBand's ability to provides real-time indoor and outdoor precise location, movement, and activity data. CareBand's system is passive, always on and does not require wi-fi or traditional cellular technology to send data to the secure HIPAA-compliant CareBand cloud. In Phase I, the PI and collaborating site, Bethany Village, will determine the feasibility and user acceptability of the device as well as the ability to correlate agitation scale data to that of CareBand's data. Aims: **1:** Engineer power-efficient firmware to collect granular motion data within a given room or hallway (e.g. pacing) and to build cloud logic to analyze this granular data for web and mobile applications. **2:** Test CareBand in the Bethany Village long-term care facility with 15 dementia patients and 15 staff members for a period of 6 weeks. **3:** Evaluate the outcomes of CareBand for usability among patients, families, and staff and its ability accurately detect agitation. At the end of Phase I, CareBand will have implemented the CareBand technology in a long term care facility environment, received feedback on the hardware and software from end users, and assessed correlation of agitation with increased patient movement . Phase II efforts will focus on construction of algorithms informed by any findings of correlation, [redacted], and a longitudinal study in multiple long-term care facilities serving individuals with ADRD. Phase II may also include [redacted] to the CareBand device for enhanced agitation measurements. A significant market opportunity exists for the CareBand technology in alerting caregivers to early signs of agitated behavior in people living with dementia, allowing caregivers to intervene before the need for psychotropic medication or hospitalization. This preemptive intervention enhances quality of life for individuals living ADRD and it decreases burden on caregivers.

Narrative

Agitation is one of the most common and distressing neuropsychiatric symptoms of Alzheimer's disease and related dementias (ADRD) for patients in the ambulatory and long-term care (LTC) settings. Agitation contributes to increased healthcare costs, greater caregiver distress and worse quality of life. A significant challenge in the management of agitation is obtaining real-time objective data on symptom patterns. CareBand is developing an end-to-end wearable technology and real-time data platform for people living with ADRD that will predict impending agitation in the ADRD patient population.

Equipment

CareBand, Inc.

No special equipment is required to complete the Aims outlined in this Phase I proposal. Items required to complete the Aims are outlined in Materials and Supplies in the Budget Justification.

Authentication of Key Biological and/or Chemical Resources

Not applicable.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Adam Sobol

eRA COMMONS USER NAME (credential, e.g., agency login): [redacted]

POSITION TITLE: CEO, CareBand

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Indiana University – Bloomington, IN	M.S	05/2016	Information Systems & Cybersecurity
Indiana University – Bloomington, IN	B.S	12/2014	Informatics & Business

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a background in software engineering and cybersecurity. I have started two software startups while in college. I currently serve as the founder and CEO of CareBand, Inc. My connection to healthcare is through my family. Growing up, I was surrounded by doctors with the largest influence being my father as a geriatrician. During weekends, I would visit the nursing home with him and go on rounds together. I was always more interested in the technology than the medical field, yet maintained a deep desire to care for people. After a conversation a few years ago, my father suggested that there is an opportunity to use this new technology, I had shared with him that Apple had recently invented, to help those living with dementia. As such, I started working on CareBand. During my time working on CareBand, I have become active in the Long Term Care community. I regularly speak about innovation in the space at meetings and conferences. I also serve on the Post-Acute/Long-term Care Society Innovation Committee where I contribute in bridging the gap between technology entrepreneurs and physician innovators. Prior to my work in healthcare, I worked as an IT Security Consultant with Protiviti Consulting. In this role, I was a part of a 10-person team running a cybersecurity penetration testing lab to discover, exploit, and fix vulnerabilities in client networks. Through this experience, I maintained a deep knowledge of cybersecurity as well as running highly confidential projects and delivering work on time. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic project plan, timeline and budget. The current application builds on my focus of commercializing CareBand and bringing it to millions of seniors living with dementia. Beyond commercializing the product, CareBand aims to significantly enhance the current research understanding of the movements, activity, and behaviors of people living with dementia across the continuum of care. Through research and strategic partnerships, CareBand hopes to enable people living with dementia to stay safe and healthy for as long as possible in the least restrictive manner possible while providing peace of mind to caregivers and family members.

Patent Applications

- Adam G Sobol; 11-27-2014; Wireless Devices and Systems for Tracking Patients and Methods for Using the Like; US20160139273A1

- Adam G Sobol; 01-05-2018; Wireless Electronic Device and System For Tracking And Identifying Changes In Salient Indicators Of Patient Health; Provisional Patent Application
- Adam G Sobol; 01-05-2018; Wearable Location and Activity Tracking Device; Design Patent Application
- Adam G Sobol; 04-12-2018; Wristband Locking Mechanism, Wristband, Wearable Electronic Device and Method of Securing an Article to a Person; Utility Provisional Patent Application

B. Positions and Honors

Positions

2016 – Present	Founder & CEO, CareBand, Inc.
2016 – 2017	IT Security Consultant, Protiviti
2014 – 2015	Indiana University School of Informatics and Computing Business Intelligence Analyst
2013 - 2014	Indiana University Auditorium Student Manager
2012 - 2014	Co-Founder & CTO, UniversityTix.com
2013 - 2014	Co-Founder & CTO, DailyFantify

Other Experience

2017 – Present	The Society for Post-Acute/Long-term Care Innovation Committee
2016 – Present	Illinois Technology Association's Internet of Things Security and Policy Committees

Honors

2017	AARP's 50+ Innovation Leaders for healthcare
2017	Chicago's 2017 Jewish 36 under 36 list
2016	Indiana University's Building Entrepreneurs in Software and Technology (BEST) [redacted]

Invited Talks

2018	Keynote for Annual Bluetooth World Conference
2018	TEDx Talk on Dementia and Technology
2016, 2017	Indiana University Technology Entrepreneurship Course Speaker
2016	Hoosier Hatchery Startup Competition Judge

C. Contributions to Science

None.

D. Additional Information: Research Support and/or Scholastic Performance

None.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CAREBAND, INC.

Start Date*: 04-01-2019 **End Date*:** 08-31-2019 **Budget Period: 1**

A. Senior/Key Person

	Prefix	First Name*	Middle Name	Last Name*	Suffix	Project Role*	Base Salary ($)	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits ($)*	Funds Requested ($)*
1 .		Adam		Sobol		PD/PI		5.1			[redacted]	[redacted]	[redacted]

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

Total Senior/Key Person [redacted]

B. Other Personnel

Number of Personnel*	Project Role*	Calendar Months	Academic Months	Summer Months	Requested Salary ($)*	Fringe Benefits*	Funds Requested ($)*
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						
1	Research Assistant	6.0			[redacted]	[redacted]	[redacted]
1	**Total Number Other Personnel**					**Total Other Personnel**	[redacted]
						Total Salary, Wages and Fringe Benefits (A+B)	[redacted]

RESEARCH & RELATED Budget {A-B} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CAREBAND, INC.

Start Date*: 04-01-2019 **End Date*:** 08-31-2019 **Budget Period: 1**

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
Total Equipment	[redacted]

Additional Equipment: File Name:

D. Travel	**Funds Requested ($)***
1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)	[redacted]
2. Foreign Travel Costs	
Total Travel Cost	[redacted]

E. Participant/Trainee Support Costs		**Funds Requested ($)***
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other:		
Number of Participants/Trainees	**Total Participant Trainee Support Costs**	[redacted]

RESEARCH & RELATED Budget {C-E} (Funds Requested)

RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 1

ORGANIZATIONAL DUNS*: [redacted]

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CAREBAND, INC.

Start Date*: 04-01-2019 **End Date*:** 08-31-2019 **Budget Period: 1**

F. Other Direct Costs	**Funds Requested ($)***
1. Materials and Supplies	[redacted]
2. Publication Costs	[redacted]
3. Consultant Services	[redacted]
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8 . Fee for Service: OptimatDesign [redacted] and Tech-Enhanced Life [redacted]	[redacted]
9 . Third Party IRB	[redacted]
10 . Bethany Village Honorarium	[redacted]
Total Other Direct Costs	[redacted]

G. Direct Costs	**Funds Requested ($)***
Total Direct Costs (A thru F)	[redacted]

H. Indirect Costs

Indirect Cost Type	**Indirect Cost Rate (%)**	**Indirect Cost Base ($)**	**Funds Requested ($)***
1 . No negotiated rate	40.0	[redacted]	[redacted]
		Total Indirect Costs	[redacted]

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs	**Funds Requested ($)***
Total Direct and Indirect Institutional Costs (G + H)	[redacted]

J. Fee	**Funds Requested ($)***
	[redacted]

K. Total Costs and Fee	**Funds Requested ($)***
	[redacted]

L. Budget Justification*	File Name: budgetjust.pdf
	(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)
Section A, Senior/Key Person	[redacted]
Section B, Other Personnel	[redacted]
Total Number Other Personnel	[redacted]
Total Salary, Wages and Fringe Benefits (A+B)	[redacted]
Section C, Equipment	[redacted]
Section D, Travel	[redacted]
1. Domestic	[redacted]
2. Foreign	[redacted]
Section E, Participant/Trainee Support Costs	[redacted]
1. Tuition/Fees/Health Insurance	[redacted]
2. Stipends	[redacted]
3. Travel	[redacted]
4. Subsistence	[redacted]
5. Other	[redacted]
6. Number of Participants/Trainees	[redacted]
Section F, Other Direct Costs	[redacted]
1. Materials and Supplies	[redacted]
2. Publication Costs	[redacted]
3. Consultant Services	[redacted]
4. ADP/Computer Services	[redacted]
5. Subawards/Consortium/Contractual Costs	[redacted]
6. Equipment or Facility Rental/User Fees	[redacted]
7. Alterations and Renovations	[redacted]
8. Other 1	[redacted]
9. Other 2	[redacted]
10. Other 3	[redacted]
Section G, Direct Costs (A thru F)	[redacted]
Section H, Indirect Costs	[redacted]
Section I, Total Direct and Indirect Costs (G + H)	[redacted]
Section J, Fee	[redacted]
Section K, Total Costs and Fee (I + J)	[redacted]

Specific Aims

An estimated 5.5 million Americans age 65 and older are living with Alzheimer's disease (AD) and as the population ages, this number is expected to rise to 13.8 million by 2050 [1]. Agitation is one of the most common and distressing neuropsychiatric symptoms of Alzheimer's disease and related dementias (ADRD) for patients in the ambulatory and long-term care (LTC) setting, with close to a quarter of patients with ADRD developing agitation throughout the course of their illness [2]. Agitation contributes to increased healthcare costs [3], greater caregiver distress [4] and worse quality of life [5]. A significant challenge in the management of agitation is obtaining objective data on symptom patterns. A family member's subjective rating of agitation may differ from that of an LTC nurse, or a consulting physician. Differences in symptom reporting can also vary according to the time of day, or be influenced by recall and other individual biases. Symptom rating scales are time consuming and frequently underutilized by LTC staff. Such subjective differences in symptom reporting makes measurement of treatment response or non-response quite difficult. *The problem is* clinicians, LTC staff and caregivers need a more cost effective, simple way to objectively measure agitation.

A recent systematic review by Khan et al. [6] examining agitation and aggression in persons with dementia using sensor technology found a positive correlation between actigraphy and agitation. The findings were limited by the small number of trials and participants, short trial duration, and lack of data on user acceptability. *What remains unknown is* whether sensor-based technology can serve as a long-term, time-efficient, and predictive approach to agitation monitoring. Furthermore, it is unclear whether patients, family, and LTC staff will accept the use of wearable sensor-based technology. To-date, none of the sensor-based technology and agitation studies reviewed by Khan, et al. have led to successful delivery of an evidence-based, commercial product to market. Patients who become agitated may be medicated with psychotropic drugs and removed from the facility; they may resort to confrontation, all of which incurs cost and distress.

CareBand, an Illinois-based small business, is developing an end-to-end wearable technology and real-time data platform for people living with ADRD. CareBand provides real-time indoor and outdoor precise location, movement, and activity data. CareBand was intentionally built for this population, from unobtrusive design (watch-like wearable) to infrastructure (small beacons and one gateway per facility). As such, CareBand's system is passive, always on and does not require Wi-Fi or traditional cellular technology to send data to the secure HIPAA-compliant CareBand cloud. CareBand has assembled a strong team that offers expertise in design, engineering, dementia care and analytics to successfully develop and commercialize this technology, filling a needed gap in sensor-based agitation surveillance and providing an opportunity for earlier clinical intervention for ADRD patients with agitation.

Due to the subjective nature multiple staff administering of agitation scales and qualitative behavior monitoring, the project team will also be collecting heartrate data via a commercially-available Nokia Steel HR device. *The central hypothesis for the project is* that agitation is highly correlated with increased patient movement, as measured through staff observations of patient agitation and the Pittsburgh Agitation Scale and intra-room and room-level movement data from CareBand devices, respectively.

In Phase I, the PI and collaborating site, Bethany Village, will determine the feasibility and user acceptability of the device as well as the ability to correlate agitation scale data to that of CareBand's data.

Aim 1: Engineer power-efficient firmware to collect granular motion data within a given room or hallway (e.g. pacing) and to build cloud logic to analyze this granular data for web and mobile applications. **Aim 2:** Test CareBand in the Bethany Village long-term care facility with 15 dementia patients and 15 staff members for a period of 6 weeks. **Aim 3:** Evaluate the outcomes of CareBand for usability among patients, families, and staff and its ability accurately detect agitation.

At the end of Phase I, CareBand will have implemented the CareBand technology in a LTC facility environment, received feedback on the hardware and software from end users, and assessed correlation of agitation with increased patient movement . Phase II efforts will [redacted], and a longitudinal study in multiple long-term care facilities serving individuals with ADRD. Phase II may also include adding heartrate sensors to the CareBand device for enhanced agitation measurements.

A significant market opportunity exists for the CareBand technology in alerting caregivers to early signs of agitated behavior in people living with dementia. These alerts allow for caregivers to intervene before the need for psychotropic medication or hospitalization. This preemptive intervention enhances quality of life for individuals living with dementia, and it decreases burden on caregivers.. There are over 32,000 assisted living, memory care, and skilled nursing communities, in which approximately 750,000 seniors with dementia reside; the total addressable market here is [redacted]. CareBand plans to refine its hardware and software and go to market in late 2019.

Research Strategy

(a) Significance

There are approximately 5.5 million Americans age 65 and older are living with Alzheimer's; this number is projected to grow to 13.8 million by 2050. In 2018, total expenditures for health care, long-term care, and hospice services for those 65 or older with dementia are approximated at [redacted] [1]. For the population of those with Alzheimer's Disease and other Related Dementia (ADRD), there has been an expansion of care options, including specialized long-term care facilities. A common change in condition in ADRD patients is agitation, defined as inappropriate verbal, vocal, or motor activity that is not judged by an outside observer to result directly from the needs or confusion of the agitated individual [6]. Wandering is also a common concern for the ADRD population. While there are several solutions on the market to address the challenges of wandering, there are few that address the challenges associated with agitation—specifically predicting impending agitation so caregivers can proactively intervene and reduce the severity of episodes before they escalate. Finally, there are no solutions on the market that use innovative technology to simultaneously address wandering and agitation.

CareBand, Inc, an Illinois-based small business, is developing a wearable technology that tracks real-time indoor and outdoor location. The device tracks individuals up to five miles without using Wi-Fi or cellular data. In addition, the individual can call a nurse or caregiver for assistance using a call button on the device. Most importantly, CareBand believes its device has the ability to track activity data that can be used to make early predictions around change in condition. Studies have shown evidence of a correlation between agitation and actigraphy, continuous measurement of activity or movement with a small device called an actigraph [6, 7]. CareBand aims to test data collection with its activity and location monitoring wearable, alongside agitation data, to establish a correlation. The goal is to construct an algorithm such that early indications of agitation and wandering can trigger an alert, and an intervention can be staged before psychotropic drugs are deployed or the situation is escalated.

Studies have shown a correlation between agitation and activity. A Belgian study published in 2006 used the Cohen-Mansfield Agitation Inventory (CMAI) and an actigraph to look for correlations between agitation and activity, while also employing the Mini Mental State Exam (MMSE) to see how cognitive function compared to activity. The researchers tracked activity in patients using an actigraph placed on the non-dominant wrist, with a plastic band that could not be removed or replaced by the subject. They found that patients with CMAI scores of 50 or greater had "clearly" higher activity levels during the day as compared to those with low total CMAI scores. Those with low MMSE scores also had higher activity scores compared to those with higher MMSE scores [8]. Another study tracked mean motor activity as well as other actigraphy measures and CMAI scores. This study found that Mean Motor Activity (MMA) in the group with high agitation was "significantly higher" than in the low agitation group, with MMA showing a strong correlation with CMAI total scores in addition to "verbal agitation and non-aggressive physical agitation scores on the CMAI" [9].

(b) Innovation

This innovative technology uses the unique combination of Bluetooth, GPS, and an internet of things (IoT) communication technology called LoRaWAN to track indoor and outdoor location in real-time without using traditional cellular or wifi technology. The use of this approach will allow location to be tracked more accurately, addressing the dangerous issue of wandering in the ADRD population. In addition, CareBand believes this combination of technology, along with heart rate detection, can be used to predict agitation.

CareBand's founder, Adam Sobol, was inspired by his father's practice of geriatric medicine and work in long term care. He started this company with the vision of keeping people living with dementia safe while providing peace of mind for families and caregivers. Providing optimal care for people living with dementia requires continuous observation of small changes in patterns of activity and behavior in order to initiate proper treatment for changes in condition. The use of smart technology which tracks real-time movement and pattern analysis algorithms has significant potential to enable early detection and changes in behavior and activity.

LoRaWAN is quickly setting itself apart from other communication technologies such as wifi or traditional cellular as it becomes tailored to IoT applications that require devices to operate in **long-range and low-power situations while remaining connected to the internet.** LoRaWAN is a great answer for remote battery-powered sensors or devices that communicate over long distances or in remote places. LoRaWAN

packages data, which is sent when needed, over long distances (up to 30 miles) to the nearest, most available gateway, and forwards packets of data to the server for storage, computation, or visualization.

CareBand has chosen to partner with Semtech, the founding partner of LoRaWAN, to provide semiconductor support. CareBand has also partnered with Comcast's IoT network service called machineQ. Through this unique partnership, machineQ has agreed to support CareBand's scale as a network infrastructure partner. Within the machineQ network coverage, there are about 20 million seniors who may be potential customers of CareBand. A recent press release from Comcast noted, "This collaboration provides CareBand with a highly scalable, reliable network that makes it easy to deploy CareBand's system in both long-term care and residential settings" [10]. CareBand has four patents pending:

Table 1: Intellectual Property Position of CareBand

Type	Date Filed	Description
Utility Patent – Pending Office Action	[redacted]	Combination of Bluetooth and GPS for indoor/outdoor tracking
Utility Provisional Patent Pending	[redacted]	Relates generally to a wearable device and corresponding system for monitoring location, environmental, physiological and activity data of a wearer of the device, and more particularly to a wearable device that wirelessly communicates data in a hybrid mode of signal transmission in order to allow data to be used to proactively identify salient indicators of changing health of the wearer of the device
Design Patent Pending	[redacted]	Form factor of the device
Utility Provisional Patent Pending	[redacted]	Lockable clasp on a band that requires two hands to open

Current technology deployed at assisted living and skilled nursing facilities are limited to door alarms and paper record of activities of daily living (ADLs). Stanley Healthcare's WanderGuard, for example, consists of multiple expensive RFID sensing readers placed on exit facing doors and elevators that create an audible alarm when a patient wearing an RFID tracking bracelet is near. The alarm is expected to alert caregivers to a patient seeking an exit. When an alarm is triggered, staff must investigate if an elopement occurred and which patient is involved. Tracking the patient location is currently not available placing the individual in a potentially dangerous situation. CareBand can employ indoor and outdoor geofences as well as alerts as to who left and exactly where they went. The system then shows the location via a Google Maps-like interface to find the patient quickly.

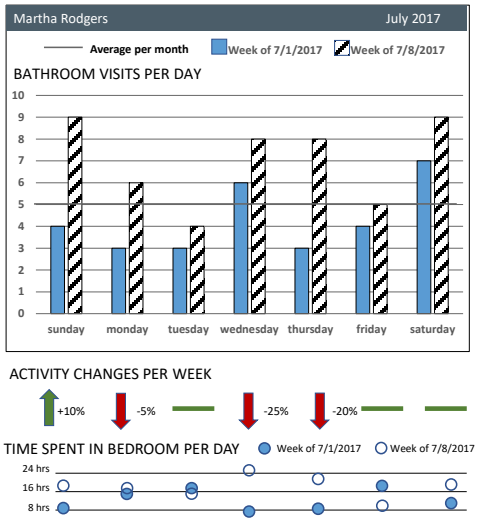


Figure 1: Tracking bathroom visits for an indication of possible UTI

There is also technology that tracks behavior without door alarm functionality. One of CareBand's competitors, for example, tracks specific ADLs uses sensors on a wrist wearable. CareBand currently offers this functionality on a limited basis. CareBand can track frequency and duration of bathroom visits and make comparisons over time. This, for example, is useful to a physician who wants insight into the onset of urinary tract infections, as demonstrated in Figure 1. "Symptoms suggestive of UTI in older adults are similar to those in younger patients, and include dysuria [painful urination] with or without frequency, urgency, suprapubic pain, or hematuria" [11, 12].

CareBand is also capable of tracking the effect of an intervention such as a drug or therapy. **No existing solution on the market offers the technology necessary to measure these tasks and behaviors**. Further, CareBand delivers clear and easy to understand dashboards and reports to easily and quickly convey the results of each patient's behavior.

c) Approach

Preliminary Studies: At the end of 2013, while he was a student at Indiana University, now CEO Adam Sobol pitched the CareBand idea at a pitch competition in Bloomington, Indiana. Though he did not get in, the idea was validated and in response, Mr. Sobol rounded up investment funds from friends and family and secured a PhD student to start development on an early prototype. He returned to the pitch competition in 2014 and won. That summer, University of Dayton engineering students were hired to create a more mature prototype. The result was a functional device, yet it was so large that it filled a shoebox. In an effort to get the device to a size and format closer to what the market would accept, Adam went to a Bluetooth World conference to seek

engineering support. There, he met an engineering firm who created CAD drawings which he was able to use to secure additional investment. A provisional patent was filed and shortly there after, a utility patent was filed.

In 2016, Adam entered Indiana University's Building Entrepreneurs in Software and Technology (BEST) competition and won a cash investment of [redacted] from 20 of the most well-known entrepreneurs in Indiana. With that traction, he raised an additional [redacted] from angel investors. He then proceeded to start engineering an alpha prototype with Optimal Design, a Chicago-based industrial design and product development firm, and was a finalist in the Louisville Innovation Summit. Subsequent patents followed and the alpha prototype was finished in December 2016.

Figure 2: Current CareBand prototype.

In 2017, CareBand was named in the "Top 10 Healthcare Tech Startups to Watch" by TechRepublic. CareBand was also a finalist at the MedCity Invest Conference and raised another [redacted] of angel investment. That same year, Adam turned an exploratory partnership with Comcast into a Master Service Agreement (MSA). At the end of 2017, Adam joined CareBand fulltime as its CEO and in 2018, CareBand was featured at the Consumer Electronics Show (CES) and selected as the American Medical Directors Association's (AMDA) 2018 Innovation Award. CareBand began to conduct limited usability pilots to collect data, first in Bloomington, Indiana and then later at Avanti, a skilled nursing and rehabilitation facility in the northern Chicago suburbs. As a result of early success in these studies, CareBand raised another [redacted].

[redacted]

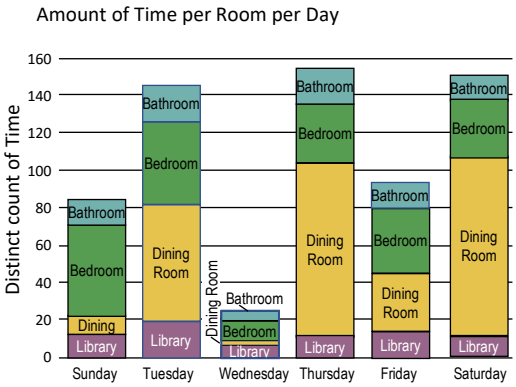


Figure 4: Tracking time spent in each room on a daily basis.

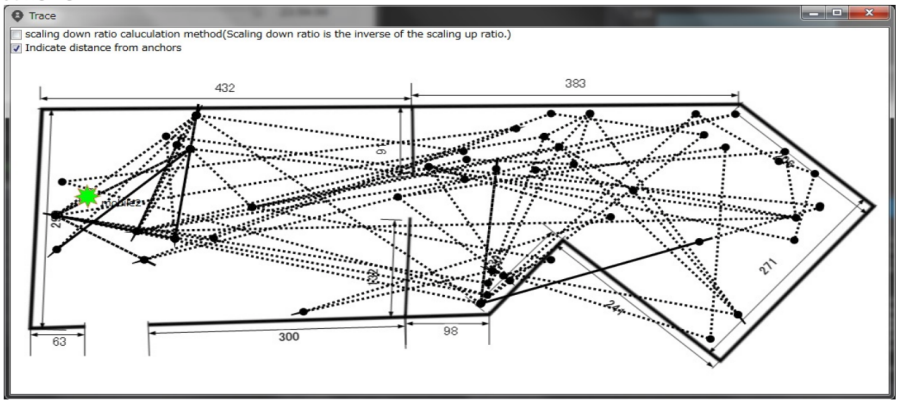


Figure 5: Intra-room pacing raw data.

Early development focused on demonstrating the feasibility of using LoRaWAN to track location and movement either in a particular room (i.e. pacing) or in a larger defined area (i.e. nursing home). Feedback has been gathered from potential partners, patients, key opinion leaders, design experts, and caregivers. This feedback has been used to complete additional design and functionality iterations of the software applications. Although preliminary, the results of early tests have demonstrated the ability to collect, analyze, and utilize location data in real-time. The following figures display actual collected data. [redacted] Figure 4 demonstrates the ability to track an individual from room to room, showing where they spend their time on a daily basis. Figure 5 demonstrates the technology's ability to record raw intra-room data. This was demonstrated by tracking an

occupational therapist at a care facility in the Chicagoland suburbs. Intra-room pacing data will be very useful to care facilities in detecting states of agitation or a need for directed activities.

Phase I Work Plan: The PI and project team will focus on further validating the feasibility of the technology and collecting movement data from patients at Bethany Village, a skilled nursing facility in Indianapolis, IN. Adam Sobol, Founder and CEO of CareBand, serves as PI. In addition, the project team includes consultants Ellen Kaehr, MD, Dan Bateman, MD, and Todd Sobol, MD, CMD.

Aim 1: **Engineer power-efficient firmware to collect granular motion data within a given room or hallway (e.g. pacing) and build cloud logic to analyze this granular data for web and mobile applications.** The CareBand device is made up of multiple electrical components including but not limited to a microprocessor, battery, sensor, antenna, etc. Depending upon the intended use case, the way in which the components interact can be altered. For example, if a facility were to want only nurse call functionality, a firmware package could be constructed and loaded onto the device to accomplish that use case. The intent of Aim 1 is to build a specific firmware package to enable the device to reliably and accurately collect granular motion data within a given room specifically without significantly sacrificing battery performance. In preliminary testing, a firmware package was created but not optimized for this use case resulting in a poor battery life of roughly 15 hours and unreliable data transfer every 3-10 minutes of movement.

To accomplish Aim 1, the PI will define the specific requirements of the use case around intra-room motion. Once documented, the PI will then create a product requirement document (PRD) stating the requirements in detail as well as additional notes of functionality of other components in the device. For example, for certain use cases there are internal algorithms to sense when a person is stationary versus moving to look for other beacon signals. If seen, the device may send a message to the cloud; if not seen, the device may sleep until a specified time to look for beacons again. These specific requirements around when the device will wake up and when the device will remain asleep will directly impact the battery performance for this use case. Other important considerations include: (1) In what format and structure are messages are sent to the LoRaWAN network? (2) How often does the device need to join the LoRaWAN network? (3) What happens to the LED lights on the device? (4) How do you know when the device is out of battery (i.e. flashing red light)? (5) What happens when the device senses the unit overheating from battery use? The answers to these questions are important and will enhance the overall firmware upon completion. After the PRD is created, the PI will work with OptimalDesign's firmware team to go over requirements and the use case. OptimalDesign is a fee for service consultancy located in Arlington Heights, IL who will assist CareBand during the project. The PI and the OptimalDesign will clarify the requirements and develop a planned approach for execution. OpitmalDesign will develop the required code for the firmware. Development of the firmware will be an iterative process, requiring several cycles of design, development, and testing. Results of early testing and quality assurance requirements will dictate changes. Once the team is confident in the package, the firmware will be loaded on the CareBand devices for execution of Aim 2. The firmware team will also create a release document noting the final measurements used in the firmware package and any specific requirements from the user.

While OptimalDesign focuses on firmware development, the PI will architect, build, and test code to ensure the intra-room firmware on the device communicates properly with the cloud to provide reliable data flow from device to application server to users. The code and logic will be developed on CareBand's existing Amazon Web Services (AWS) cloud infrastructure. The PI will develop a PRD and plan to complete the project of architecting, building, and testing the intra-room data flow. Next, the PI will select specific AWS services and web technologies to accomplish the stated requirements. Once confident in the technology, the PI will begin to build out the cloud logic and code required to move the data from the device to the application server. As a part of the process, the PI will build a specific API in which the web and mobile applications for users can interact with the application server. During this phase, the PI will transform raw data into readable data for end users. Lastly, the PI will incorporate the API into the existing web and mobile applications for display of data for users.

Aim 1 Milestone, Potential Pitfalls and Alternative Strategies: The milestone for Aim 1 will focus on the development of the firmware that works with existing battery limitations and hardware design to support granular motion data. Changes in the firmware may negatively impact the battery life, resulting in lifespans as low as 15 hours. If this happens, the team will devise a charging strategy to be used during the Phase I study and further develop the battery in additional iterations in Phase II and beyond. While a battery life of <48 hours is not ideal, it will not interfere with the overall goal of Phase I, which is data collection and analysis.

Aim 2: **Test CareBand in the Bethany Village long-term care facility with 15 dementia patients and 15 staff members for a period of 6 weeks.** This Aim will require three months and is described below: preparation (4 wks), study (6 wks), and wrap up (2 wks). Dr. Ellen Kaehr will lead this study at Bethany Village.

Preparation: First, the PI will work to set up, install, and initialize Bethany Village for the study. This process includes installing multiple beacons in each room and hallway in a manner that supports the intra-room motion capture. The PI will install a single LoRaWAN gateway via ethernet connection in the facility (the size of a router box). Next, the PI will create a digital map of the facility, set up staff accounts and test the beacons in the system. At each nursing station, a tablet will be set up for viewing the CareBand web application with the indoor and outdoor map of patients, device details including battery levels, and nurse call information. Next, the PI will work with Dr. Kaehr and the Director of Nursing to conduct training session for 15 staff recruited to participate in the study. Sessions will be offered at varied times to accommodate staff shifts and will last between 30 and 45 minutes. Each session will include a discussion of attaching a patent-pending two-handed clasp, charging and charging cadence, administration of the Pittsburgh Agitation Scale (PAS), and recording of qualitative agitation data. The PAS asks about the intensity of four behavior groups as well as whether any specific interventions were used due to problems in behavior [13]. Scale data and qualitative replies will be recorded on paper. Guided walk-throughs and how-to sheets will be printed out and placed at the nursing stations for staff to reference throughout the study.

Depending on the optimizations of the firmware package, the nurse call functionality may be enabled or disabled. In the event it is enabled, the top of the device will be a button that can be pressed by the patient to alert the staff to their need for assistance. Additionally, each staff member will receive an RFID-like card that they will keep with them to clear the nurse call alert. Due to the subjective nature of various staff administering the Pittsburg Agitation Scale, participants will also wear the Nokia Steel heart rate (HR) device to support objective heart rate measurements throughout the study. Although there are a plethora of factors (i.e. medication, heart conditions, exercise, etc.) that can change HR, having this additional measurement will help support analysis in Aim 3. Additionally, if capturing HR proves useful, an HR sensor will be embedded in the next design iteration of the CareBand. The Nokia Steel HR devices are commercially available wearable devices that can be affixed beneath the CareBand or on the opposing wrist of patients. The device will collect HR data on an ongoing basis; the PI will extract data collected approximately every 20 days during charging. Next, Dr. Sobol and Dr. Kaehr (Medical Director at Bethany Village) will identify patients for recruitment into the study. Dr. Ellen Kaehr will use Brief Interview for Mental Status (BIMS) completed in the last quarter for patients with dementia. BIMS is an evidence-based and performance-based cognitive screen that can easily be completed by nursing home staff. The goal of the BIMS is to create a cognitive baseline, identify patients who need further cognitive evaluation and identify change in cognition on at least a quarterly basis and potentially more frequent due to condition change. Tracking the BIMS allows the CareBand study team to gain insight into the patient's cognitive status at the time of intervention. Dr. Kaehr will consult with the Director of Nursing, Executive Director, and Memory Care Coordinator regarding the list of patients identified to determine who meets the additional inclusion/exclusion criteria, including being ambulatory, ability to provide verbal feedback and have an involved family member/guardian or advocate. Consent will be obtained for 15 patients either by the participant, family, or specified power of attorney.

Study: The study will run for a period of six weeks with a total of 15 patients. During the study, each stakeholder will have specific tasks. The staff will have three key tasks to complete. 1) Each 8-hour shift during each day, staff will complete the Pittsburgh Agitation Scale once per patient. 2) Each 8-hour shift, staff will note qualitative observations of agitation in patients on paper sheet at the nursing station. 3) Depending on the firmware package, staff will be responsible for charging the device once a day or once every three days. Dr. Kaehr will oversee the staff, check in on the patient's comfort with the device, and collect Pittsburgh Agitation Scales and Qualitative feedback sheets. Once a week, Dr. Kaehr will formally meet with the PI and include optionally the Executive Director and Director of Nursing for an update on the study. The PI will ensure the devices, web and mobile apps are performing as intended. The PI will troubleshoot or fix issues as they arise.

Wrap Up: At the end of the study, the PI will remove all CareBand infrastructure in each room and hallway of the building. The PI will also remove all tablets from nurse's stations and devices from patients. Dr. Kaehr will remove the binders and any other materials related to the study from staff.

Aim 2 Milestone, Potential Pitfalls and Alternative Strategies: The milestone for Aim 2 is the completion of the study with 15 patients successfully enrolled and participating for six weeks with both HR data and

CareBand data successfully collected. A potential pitfall may be recruitment and retention of study subjects. However, Dr. Kaehr is the Medical Director of Bethany Village, is familiar with the patient census, and feels confident that the enrollment target is reasonable. An additional potential pitfall could be lack of routine data capture. To ensure data is being captured, CareBand will do intermittent data checks early in the study. Once the team is confident the data is being collected as planned, the data checks will no longer be necessary.

Aim 3: **Evaluate the outcomes of CareBand for usability among patients, families, and staff and its ability to accurately detect agitation.** Focus group workshops will be designed and facilitated by a third party. Dr. Richard G. Caro (CEO Tech-Enhanced Life) offers experience in leading group interactions that include older adults with ADRD as well as their families, friends, and caregivers.

Three groups will participate in the focus groups: patients in the study (30 minute sessions), family members (one to two hours), and participating staff (one to two hours). Participants will each receive a [redacted] gift card at the conclusion of their focus group session. Audio will be recorded and later transcribed by Tech-Enhanced Life. With patients, Dr. Caro will focus on the comfort of CareBand as well as exploring perspective around dignity, safety and privacy. With family members, questions will be similar with the addition of the topic, peace-of-mind. With staff, questioning will be around behaviors of patients, the perceived utility of the technology both before and after use, and usability of the software. Analysis of this data will include representative quotations grouped by theme [14]. This data analysis piece will be driven by the question: can CareBand data accurately detect agitation in patients living with dementia? More specifically, the PI will aim to investigate the hypothesis that agitation is highly correlated with increased patient movement, as measured through staff observations of patient agitation and the PAS and intra-room and room-level movement data from CareBand devices, respectively. The goal of this aim is to investigate whether this correlation exists. If proven to exist, Phase II will focus on building a predictive model to predict impending agitation, allowing alerted staff to intervene before the use of psychotropic drugs or hospitalization becomes necessary.

To investigate the hypothesis, the PI, Dr. Kaehr and Dr. Bateman will use the data collected throughout the steps outlined above. The four types of data collected are 1) intra-room and room-level movement data; 2) heart rate data; 3) Pittsburgh Agitation Scale data; and 4) qualitative observation data. The PI and Dr. Sobol will work to clean and transform the raw data into usable measurement data for further analysis. For example, the PI will take the raw movement data, which consists of x, y coordinates, room number IDs and timestamps, and transform it into specific measurements of movement or activity. Data will be organized by eight-hour shifts, with an entry in the data for each shift-day-patient combination. Once transformed into a usable format, the PI will work with the RA to employ statistical tests to determine the best possible way to analyze the data. These tests may include, but are not limited to, a multivariate regression or a chi-squared test for independence. Finally, the PI, Dr. Kaehr, Dr. Bateman and RA will interpret the results of the statistical tests to determine to what extent, if at all, the hypothesis is correct.

Aim 3 Milestone, Potential Pitfalls and Alternative Strategies: At the end of this Aim, CareBand will have demonstrated the feasibility and usability of the device. This will be demonstrated through data collected and analyzed, and feedback from actual end users participating in the study. A potential problem may arise if data has not been accurately or regularly collected throughout the study. To avoid this pitfall, the team will make regular data checks throughout Aim 2 to ensure the required data is available to complete Aim 3.

Summary: At the end of Phase I, CareBand will have implemented the CareBand technology in a long term care facility environment, received feedback on the hardware and software from end users, and assessed correlation of agitation with increased patient movement. Phase II efforts will focus on construction of algorithms informed by any findings of correlation, the creation of a predictive model around predicting impending agitation, and a long-term study in multiple long-term care facilities serving individuals with ADRD. Phase II may also include adding heartrate sensors to the CareBand device for enhanced agitation measurements.

Table 2: Addressable Markets

Market	Market Size	Market Potential
Assisted Living & Memory Care	300,000	[redacted]
Skilled Nursing Homes	450,000	
Home Healthcare Agencies	4.5 Million	

Commercialization: Dementia care is a large and growing market. CareBand will initially target sales of the device directly to senior living facilities. Once successfully integrated in to 25 communities (having had conversations thus far with ten of the nation's leading assisted living providers who own close to 500 facilities), CareBand will seek a distribution partner to support sales, installation and maintenance support.

CENTER FOR AGING RESEARCH
INDIANA UNIVERSITY

Regenstrief Institute

September 1, 2018

Mr. Adam Sobol
CareBand, Inc
[redacted]

Re: "CareBand: Wearable Technology for People with Dementia"

Dear Mr. Sobol,

I am writing in support of CareBand's SBIR proposal, "CareBand: Wearable Technology for People with Dementia"

Through my positions at the Indiana University Center for Aging Research, School of Medicine, and Center for Aging Research, I study the design and implementation of novel, effective interventions to treat the neuropsychiatric symptoms of dementia and the utilization of technology to help older adults age in place, maintain their independence and improve their quality of life. I am a board-certified geriatric psychiatrist; Assistant Professor of Psychiatry; a clinician at the Sandra Eskenazi Center for Brain Care Innovation at Eskenazi Health and a Co-Investigator of the Indiana Alzheimer's Disease Center, Outreach and Recruitment core. Helping patients and families navigate the complexities, disease course and treatment options for neurocognitive disorders and mental illness are among the most rewarding aspects of my work.

As a consultant and team member, I will work with geriatrician colleague and Co-I, Dr. Ellen Kaehr and other CareBand team members to design and implement a human subjects research study to assess the feasibility and usability of CareBand for individuals with dementia and to determine the accuracy of CareBand in measuring agitation in this population. The study will take place at the Bethany Village long-term care facility where Dr. Kaehr is medical director. As a geriatric psychiatrist specializing in dementia care I will serve as a neuropsychiatric symptom expert for the study and will reach out to my large network of clinical colleagues should the study require additional consultation. We have agreed that if our SBIR proposal is funded [redacted] will be used support me presenting our findings at either national or international conferences.

Regarding this study, I am very enthusiastic about the prospect of using CareBand in the dementia population to reduce risk of wandering and to monitor agitation. Such a system is essential to improving the longitudinal measurement of neuropsychiatric symptoms and to ultimately advancing the treatment of individuals with dementia. This proposal fits perfectly with my philosophy of empowering patients while caring for their health. I am therefore most excited about being part of this important study and working together on the testing of CareBand.

Sincerely,

[redacted]

Daniel R. Bateman, MD
Assistant Professor of Psychiatry, Indiana University School of Medicine

OptimalDesign

[redacted]

September 2, 2018

CareBand
[redacted]

Re: CareBand: Wearable Technology for People with Dementia

Dear CareBand:

We write to express our full support of your SBIR application entitled “CareBand: Wearable Technology for People with Dementia”.

OptimalDesign will provide firmware development and hardware support for [redacted]. The code underlying the firmware will be iteratively written and tested in-unit by our team, under the direction of PI Mr. Adam Sobol. We will provide the needed CareBand devices and bands.

OptimalDesign is based in Arlington Heights, Illinois, and has partnered with CareBand as its industrial design and product development firm, developing the alpha and beta prototypes and strategizing around future changes. We have diverse team of industrial design, mechanical engineering, electrical engineering, and RF engineering. Additionally, we have capacity to do low volume manufacturing.

We look forward to working with Mr. Adam Sobol, his team at CareBand, and other collaborators on this project.

Sincerely,

JD Sims
OptimalDesign
Business Development Manager
[redacted]

Tech-enhanced Life

August 30, 2018

Mr. Adam Sobol
CareBand
[redacted]

Re: CareBand: Wearable Technology for People with Dementia

Dear CareBand,

This letter is in support of the SBIR application entitled "CareBand: Wearable Technology for People with Dementia".

Tech-enhanced Life will participate in three focus group workshops before CareBand implementation, and three workshops once data collection is complete. I will personally design and facilitate each. Each set of three workshops will consist of the following: residents participating in the study (30 minutes), a family member of each resident (1-2 hours), and staff involved in the care of these residents (1-2 hours). The fee for service for the above is [redacted], with an additional [redacted] allocated for travel expenses. The total fee for service is [redacted].

By way of background, as CEO of Tech-enhanced Life I have extensive experience of leading group interactions (and one-on-one interactions) that include older adults, as well as on occasion their families, friends, and caregivers. In total, over the last 4 years I have facilitated well over 150 of these types of interaction, including a number that include product feedback of various sorts. As part of this body of research we have experience interacting with older adults with cognitive impairment, which will be an important skill for this project.

We look forward to working with the team at CareBand on this project.

Sincerely,

[redacted]

Dr. Richard G. Caro
CEO, Tech-enhanced Life
[redacted]

machineQ
A COMCAST SERVICE

4 September, 2018

CareBand
[redacted]

Re: CareBand

Dear Adam,

This letter is in support of the SBIR application titled "CareBand: Wearable Technology for People with Dementia".

machineQ believes this project presents offers an important opportunity to make a significant and needed contribution to the field. The proposal can greatly improve patient's care and quality of life.

Our team at machineQ has had ongoing conversations with CareBand's founder, Adam Sobol, as well as have provided strategic level support to the CareBand team. Our core function is to deliver the LoRa connectivity foundation to enable their healthcare solution.

Sincerely,

[redacted]

Jacob Murphy
Sr. Manager of Business Development
[redacted]

August 23, 2018

Mr. Adam Sobol, Founder & CEO
CareBand
[redacted]

Re: NIH STTR Grant Application

Dear Mr. Sobol:

I am writing this letter as Board Chair of the Dementia Action Alliance in support of your SBIR application entitled "CareBand: Wearable Technology for People with Dementia".

The Dementia Action Alliance (DAA) is a non-profit national advocacy and education organization of people living with dementia, care partners, organizations, companies, and dementia specialists committed to inclusion, person- and relational-centered care practices, identifying beneficial technologies to accommodate individuals' changing abilities, and collaboration. **https://daanow.org/our-mission/**

CareBand is an active member of our Corporate Leadership Council, which brings together innovative and progressively-minded leaders with individuals living with early to moderate symptoms of dementia to: advance information about emerging trends, opportunities and challenges in the industry; ensure feedback from those living with dementia for their products/services; and provide access to white papers, research findings and other relevant resources.

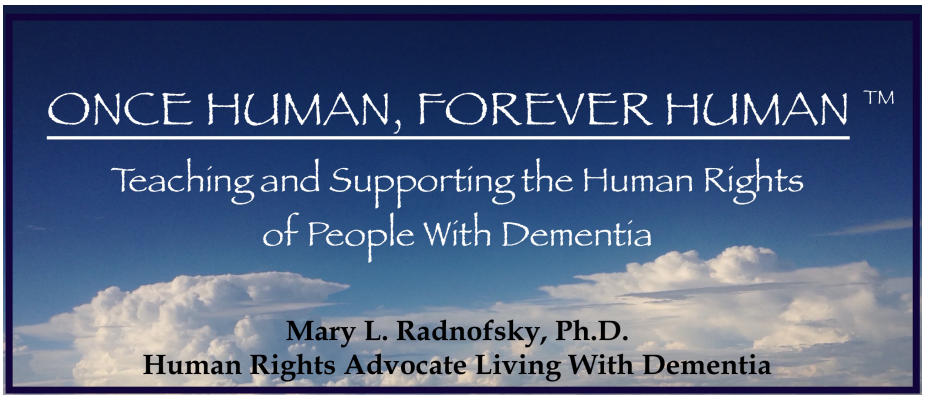
DAA knows that CareBand technology enhances safety and quality of life for those living with dementia. We believe this project represents an important opportunity to glean significant data about its users and better enable providers to evaluate said data for advancing user safety and enhancing individualized approaches to care and quality of life.

DAA is committed to advancing CareBand's visibility and promoting its use throughout our extensive network of providers and professionals committed to optimizing health and well-being for individuals and families living with one of the most significant conditions impacting society in this century.

Sincerely,

Jackie Pinkowitz

Jackie Pinkowitz, M.Ed.
Board Chair, Dementia Action Alliance [redacted]



August 28, 2018

CareBand
[redacted]

I am pleased to fully and unconditionally recommend the project, "CareBand: Wearable Technology for People with Dementia," to the NIH SBIR for studying the feasibility of monitoring and addressing the changing needs in individual wellbeing and care for the quickly-growing population of people with degenerative brain diseases.

As a woman living independently with younger-onset dementia for over 12 years, I wish to remain autonomous for as long as possible, of course. Yet I need to know I'm not alone in case of emergency. CareBand, with its unique potential to grant freedom to a person such as myself living with a cognitive disability, can provide me both with a passive and active connection to a monitoring service, medical expert, and/or family member, without intruding on my privacy.

My international advocacy for dementia rights includes ensuring that we have equal access to health care. What has impressed me with the CareBand project since early 2018 is that Mr. Sobol recognizes the need to balance medical care with human social, emotional, and privacy rights. Since we've met and spoken on several occasions, I've grown to trust in his integrity and creativity to expand the capacity of CareBand beyond locating individuals, to include identifying (and even anticipating) the medical or social needs of wearers, while respecting those rights. This is especially important when dementia or accidents leave us unable to ask for help, such as in cases of aphasia, stroke, abduction, blackout, terrorist attack, or natural disaster, thus leaving disabled people at an inherently unfair and inhumane disadvantage for survival.

Well-placed technology can create equality for people with disabilities, so we can enjoy the same opportunities and human rights as other people already have. Those of us with cognitive disabilities may not always be able to solve problems or find the nearest exit while under stress, alone, or scared, but if we have CareBand as a vital connection to lifesaving services, we have a better chance to survive, and someday thrive again. To achieve that possibility, I commit to consulting with CareBand as long as I can continue to provide firsthand insights to the needs and rights of people with cognitive disabilities.

Warmest Regards,
Mary L. Radnofsky, Ph.D.
Human Rights Advocate
[redacted]

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Resource Sharing Plan

Proprietary components of this application will not be released in accordance of the Small Business Act. All scientific results obtained from the proposal will be presented at scientific meetings and published in peer-reviewed scientific journals in a timely manner and acknowledge that the NIH supported the research. Additional details on the collection, analysis and interpretation of the data as a result of this project can be found in the Research Plan.

Select Agents

Not applicable.

Facilities and Other Resources

CareBand, Inc.
CareBand is located in [redacted] and is a member of MATTER, a healthcare startup incubator operating out of [redacted] MATTER embeds its member companies within a large community of healthcare professionals including pharmaceutical, medical device, diagnostics, and health IT companies; venture capitalists; health systems and hospitals; payers; scientists; and physicians.

Laboratory: Not Applicable

Clinical: Not Applicable

Animal: Not Applicable

Computer: CareBand team members each have an individual laptop dedicated to company-related efforts. These laptops are used at MATTER using its secure server with password protection and including all peripherals, printers, scanners, data storage devices, etc.

Office: CareBand's dedicated office space is located at MATTER [redacted] MATTER occupies 25,000 square feet in [redacted]. At MATTER, the CareBand team has access to typical office services including meeting facilities, a printing station, and phone booths. Additional resources include storage and receiving areas and a kitchen facility. CareBand's space at MATTER includes a locking file cabinet in which all project-related materials will be stored.

Other: As a member of MATTER, CareBand also benefits from access to mentors-in-residence—a wide variety of professionals with extensive expertise in healthcare, technology, and entrepreneurship . In addition, MATTER hosts several events throughout the year exclusively for its members that provide opportunities to connect directly with investors and leaders in the health IT industry.

Bethany Village
Bethany Village is a 100-licensed bed skilled nursing facility on the [redacted]. The facility includes rehabilitation, memory care, long-term care, respite care, hospice care, and outpatient therapy. Relevant to this project, Bethany Village offers a 26-bed Dementia Neighborhood, Auguste's Cottage. This neighborhood offers stable staffing levels and structured activity programming with policies and procedures influenced by dementia and Alzheimer's care expert Teepa Snow.

Just In Time Report

Report submitted on : 08/07/2019 11:40 AM

IRB Confirmation:

Human Subjects Assurance Number:

IACUC Confirmation: No IACUC Certification was required

OTHER SUPPORT

SOBOL, A. G.

ACTIVE

None

PENDING

[redacted]

OVERLAP

None

Just in Time Request
CareBand, Inc.
R43AG063685
Principal Investigator: Adam Sobol

EVALUATION OF FINANCIAL MANAGEMENT SYSTEMS (Abbreviated Questionnaire)*			
	YES	NO	COMMENT
A. ACCOUNTING SYSTEM:			
1. Is there a chart of accounts?	X		
2. Does the accounting system include a project cost ledger providing for the recording of expenditures for each program by required budget cost categories?	X		
3. How do employees account for their time and effort? Please explain.			Employees will keep time sheets with time recorded, by project and task, in quarter-hour increments. Timesheets will be signed by the employee and submitted to a supervisor for approval and submission for payment.
B. FINANCIAL CAPABILITY:			
1. Does the organization prepare financial statements at least annually? (Provide a copy of latest Balance Sheet and Income Statement.)	X		
2. Has the organization established line(s) of credit? If so, identify source and amount.		X	
C. BUDGETARY CONTROLS:			
1. Are there budgetary controls in effect (e.g. comparison of budget with actual expenditures on a monthly basis) to preclude drawing down federal funds in excess of:			
a. Total funds authorized on the Notice of Grant Award;	X		A third party accounting firm has been engaged to track spending against the authorized grant spending. Requests for draw downs will be prepared and approved by the Project Manager prior to submission. Monthly reports of expenditures and balances by category (for grant spending) will be prepared by the third party accounting firm.
b. Total funds available for any cost category if restricted on the Notice of Grant Award.	X		
D. INTERNAL CONTROLS			
1. What safeguards has the grantee instituted to ensure adequate internal controls in the company? Please describe. Some examples might be:			
a. Accounting entries are supported by appropriate documentation; e.g. purchase orders and vouchers.			A third party accounting firm has been engaged to manage the finances of the company. The accounting firm works directly with the company manager to track the financial position of the company and follow GAAP in record keeping, time keeping and the retention of financial information. Accounting entries valued at over [redacted] will require a purchase order and all entries will require a receipt, corresponding invoice or other proof of purchase. The manager will provide the accounting firm with information to make entries. The accounting firm will make entries and prepare reports. Monthly reconciliation reports will be approved by the manager and CEO and quarterly reports will be shared with the board of corporate officers and business advisors.
b. Separation of responsibility in the receipt, payment, and recording of cash.			
c. Other			

CareBand Inc.

PROFIT AND LOSS

January 1 - August 6, 2019

	TOTAL
Income	
Sales	[redacted]
Service	[redacted]
Total Income	[redacted]
GROSS PROFIT	[redacted]
Expenses	
Accounting Fees	[redacted]
Contractors	[redacted]
Legal & Professional Fees	[redacted]
Office Expenses	[redacted]
QuickBooks Payments Fees	[redacted]
Rent or Lease	[redacted]
Total Expenses	[redacted]
NET OPERATING INCOME	[redacted]
NET INCOME	[redacted]

CareBand Inc.

BALANCE SHEET

As of August 6, 2019

	TOTAL
ASSETS	
Current Assets	
Bank Accounts	
OPERATING ACCOUNT [redacted]	[redacted]
SVB Cash Sweep Account [redacted]	[redacted]
[redacted]	
Total Bank Accounts	[redacted]
Accounts Receivable	[redacted]
Other Current Assets	[redacted]
Total Current Assets	[redacted]
Other Assets	
Accumulated Amortization	[redacted]
R&D	[redacted]
Software Design & Development	[redacted]
Total Other Assets	[redacted]
TOTAL ASSETS	[redacted]
LIABILITIES AND EQUITY	
Liabilities	
Long-Term Liabilities	
Shareholder Notes Payable	[redacted]
Total Long-Term Liabilities	[redacted]
Total Liabilities	[redacted]
Equity	
Common Stock	[redacted]
Opening Balance Equity	[redacted]
Retained Earnings	[redacted]
Net Income	[redacted]
Total Equity	[redacted]
TOTAL LIABILITIES AND EQUITY	[redacted]

Federally Negotiated Indirect Rate
CareBand does not yet have an established indirect cost rate with a federal agency. Based upon a projection of the facilities and administration activities and costs projected for the next year, the company applied the allowable indirect cost rate of 40% to the Phase I budget.

Other Support
Other Support is included for Adam Sobol. There are no changes to the key personnel on this project, therefore no additional Other Support or biographical sketches are included.

HHS Small Business Innovation Research Program
Life Cycle Certification

All SBIR Phase I and Phase II awardees must complete this certification at all times set forth in the funding agreement (see §8(h) of the SBIR Policy Directive). This includes checking all of the boxes and having an authorized officer of the awardee sign and date the certification each time it is required. Awardees are not required to submit this certification directly to NIH but must instead complete the certification and maintain it on file in accordance with the records and retention policy in Section 8.4.2 of the NIH Grants Policy Statement or as listed in the SBIR contract solicitation or contract award.

A certification is required at the following times:

- For SBIR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System or via contract.
- For SBIR Phase II Awardees: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System or via contract.

In addition, SBIR awardees indicate compliance with these certification requirements by drawing or requesting funds from the Payment Management System. If the grantee cannot complete this certification or cannot ensure compliance with the certification process, it should notify the funding agreement officer immediately. If resolution cannot be reached, the funding agreement officer will void or terminate the award, as appropriate.

Grant or Contract Number: R43AG063685

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)): Sobol, Adam

Please read carefully the following certification statements. The Federal government relies on the information to ensure compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, the SBIR Policy Directive, and also any statutory and regulatory provisions referenced in those authorities.

If the funding agreement officer believes that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The principal investigator spent more than one half of his/her time as an employee of the awardee or has requested and received a written deviation from this requirement from the funding agreement officer.

   ☒ Yes ☐ No Deviation approved in writing by funding agreement officer: %

2. All, essentially equivalent work, or a portion of the work performed under this project (check the applicable line):

   ☒ Has not been submitted for funding by another Federal agency.

   ☐ Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

   ☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the funding agreement officer.

3. Upon completion of the award it will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the funding agreement officer (check the applicable line and fill in if needed):

   ☒ SBIR Phase I: at least two-thirds (66 2/3%) of the research

   ☐ SBIR Phase II: at least half (50%) of the research

   ☐ Deviation approved in writing by the funding agreement officer: %

4. The work is completed and it has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the funding agreement officer (check the applicable line and fill in if needed).

   ☐ SBIR Phase I: at least two-thirds (66 2/3%) of the research

   ☐ SBIR Phase II: at least half (50%) of the research

   ☐ Deviation approved in writing by the funding agreement officer: %

   ☒ N/A because work is not completed

5. The research/research and development is performed in the United States unless a deviation is approved in writing by the funding agreement officer.

   ☒ Yes ☐ No ☐ Waiver has been granted

6. The research/research and development is performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the Notice of Award or Contract Award.

   ☒ Yes ☐ No

☒ I will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

☒ I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

☒ I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2)

treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

8/6/2019 Date
Signature [redacted]
Adam Sobol Printed Name (First, Middle, Last)
CEO Title
CareBand, Inc. Business Name

SBIR Funding Agreement Certification

Grant Contract Number: R43AG063685

Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)): Sobol, Adam

All small businesses that are selected for award of an SBIR funding agreement must complete this certification at the time of award and any other time set forth in the Notice of Award or Contract Award that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on this information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions references in those authorities.

If the Grants Management or Contracting Officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Grants Management or Contracting Officer believes, after award, that the business is not meeting certain Notice of Award requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil, or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The business concern meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☒ Yes ☐ No

2. If a corporation, all corporate documents (articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☒ Yes ☐ No ☐ N/A Explain why N/A:

3. If a partnership, the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☐ Yes ☐ No ☒ N/A Explain why N/A:

4. If a limited liability company, the articles of organization and any amendments, and operating agreements and amendments, evidence that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.

   ☐ Yes ☐ No ☒ N/A Explain why N/A:

5. The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States.

   ☒ Yes ☐ No ☐ N/A Explain why N/A:

6. It has no more than 500 employees, including the employees of its affiliates.

   ☒ Yes ☐ No

7. SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard.

   ☒ Yes ☐ No

8. During the performance of the award, the principal investigator will spend more than half of his/her time as an employee of the awardee or has requested and received a written deviation from this requirement from the Grants Management or Contracting Officer.

   ☒ Yes ☐ No Deviation approved in writing by Grants Management or Contracting Officer: %

9. All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):

   ☒ Has not been submitted for funding by another Federal agency

   ☐ Has been submitted for funding by another Federal agency but has not been funded under any other Federal grant, contract, subcontract, or other transaction.

   ☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Grants Management or Contracting Officer.

10. During the performance of award, it will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Grants Management or Contracting Officer (check the applicable line and fill in if needed):

    ☒ SBIR Phase I: at least two-thirds (66 2/3%) of the research

    ☐ SBIR Phase II: at least half (50%) of the research

    ☐ Deviation approved in writing by the Grants Management or Contracting Officer: %

11. During performance of award, the research/research and development will be performed in the United States unless a deviation is approved in writing by the Grants Management or Contracting Officer.

    ☒ Yes ☐ No

12. During the performance of award, the research/research and development will be performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the Notice of Award or Contract Award.

    ☒ Yes ☐ No

13. It has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms.

    ☐ Yes ☒ No ☐ N/A Explain why N/A:

14. It is a Covered Small Business Concern (a small business concern that: (a) was not majority-owned by multiple venture capital operating companies (VCOCs), hedge funds, or private equity firms on the data on which it submitted an application in response to an SBIR solicitation; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the solicitation, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms).

    ☐ Yes ☒ No

15. It will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

☒ Yes ☐ No

I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180; and (6) other administrative penalties including termination of SBIR/STTR awards.

2019-08-06 Date
Signature [redacted]
Adam Sobol Printed Name (First, Middle, Last)
CEO Title
CareBand, Inc. Organization Name

NIH & CDC Small Business Innovation Research Program
Certification for Applicants That Are Majority-Owned by Multiple Venture Capital Operating Companies, Hedge Fund, or Private Equity Firms

Any small businesses that are majority-owned by multiple venture operating companies (VCOCs), hedge funds or private equity firms and are submitting an application for an SBIR funding agreement must complete this certification prior to submitting an application. This includes checking all of the boxes and having an authorized officer of the applicant organization sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) Program award and meets the specific program requirements during the life of the funding agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 C.F.R. Part 121), the SBIR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the funding agreement officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), who will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the funding agreement officer believes, after award, that the business is not meeting certain funding agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked):

1. The applicant is NOT more than 50% owned by a single VCOC, hedge fund or private equity firm.

   ☒Yes ☐No

2. The applicant is more than 50% owned by multiple domestic business concerns that are VCOCs, hedge funds, or private equity firms.

   ☐Yes ☒No

3. I have registered with SBA at www.SBIR.gov as a business that is majority-owned by multiple VCOCs, hedge funds or private equity firms.

   ☒Yes ☒No

☒ I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes.

☒ All the statements and information provided in this form and any documents submitted are true, accurate and complete. If assistance was obtained in completing this form and the supporting documentation, I have personally reviewed the information and it is true and accurate. I understand that, in general, these statements are made for the purpose of determining eligibility for an SBIR funding agreement and continuing eligibility.

☒ I understand that the certifications in this document are continuing in nature. Each SBIR funding agreement for which the small business submits an offer or application or receives an award constitutes a restatement and reaffirmation of these certifications.

☒ I understand that I may not misrepresent status as small business to: 1) obtain a contract under the Small Business Act; or 2) obtain any benefit under a provision of Federal law that references the SBIR Program.

☒ I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the SBIR applicant or awardee, that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to:

(1) fines, restitution and/or imprisonment under 18 U.S.C. §1001;

(2) treble damages and civil penalties under the False Claims Act (31 U.S.C. §3729 et seq.);

(3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. §3801 et seq.);

(4) civil recovery of award funds,

(5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. part 180); and

(6) other administrative penalties including termination of SBIR/STTR awards.

My signature is verification that the statements checked (☒) above are true and complete. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

2019-08-06 Date
Signature 
Adam Sobol Printed Name (First, Middle, Last)
CEO Title
CareBand, Inc. Organization Name

CITI PROGRAM

Completion Date 09-Feb-2019
Expiration Date 08-Feb-2022
Record ID 30461271

This is to certify that:

Adam Sobol

Has completed the following CITI Program course:

Human Research (Curriculum Group)
Social/Behavioral Researchers (Course Learner Group)
1 - Stage 1 (Stage)

CITI
Collaborative Institutional Training Initiative

Under requirements set by:

Indiana University/IU Health

Verify at www.citiprogram.org/verify/?wabe58184-a061-41c8-8216-b8b88b532ee2-30461271

CITI PROGRAM

Completion Date 09-Feb-2019
Expiration Date N/A
Record ID 30461270

This is to certify that:

Adam Sobol

Has completed the following CITI Program course:

Social and Behavioral Responsible Conduct of Research (Curriculum Group)
Social and Behavioral Responsible Conduct of Research (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Indiana University/IU Health

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w9eadf16b-a590-4cd9-bf4d-3ac43fad2b3a-30461270

Just In Time Report

Report submitted on : 07/15/2019 07:32 AM

IRB Confirmation:

Human Subjects Assurance Number:

IACUC Confirmation: No IACUC Certification was required

Targeted/Planned Enrollment Table

This form is now completed within the forms packet. Please complete this table for each study as a draft (I will add it to the forms packet)

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:	CareBand: Wearable Technology for People with Dementia
Domestic/Foreign:	Domestic
Comments:	

Racial Categories	**Ethnic Categories**				
	Not Hispanic or Latino		**Hispanic or Latino**		
	Female	**Male**	**Female**	**Male**	**Total**
American Indian/Alaska Native					
Asian	1	1			2
Native Hawaiian or Other Pacific Islander					
Black or African American	4	3			7
White	9	8	1	1	19
More than One Race			1	1	2
Total	**14**	**12**	**2**	**2**	**30**

Just In Time Report

Report submitted on : 07/15/2019 07:18 AM

IRB Confirmation:

Human Subjects Assurance Number:

IACUC Confirmation: No IACUC Certification was required

OTHER SUPPORT

SOBOL, A. G.

ACTIVE

None

PENDING

[redacted]

OVERLAP

None

KAEHR, E. W.

ACTIVE

1E1CMS331488-03-00 (Unroe) 03/21/16-10/23/20 1.2 calendar
DHHS-CMS [redacted]
Initiative to Reduce Avoidable Hospitalizations among Nursing Facility residents – Payment Reform
The purpose of this project is to implement and test a new payment model with the goal of improving the health and health care among LTC facility residents and ultimately reducing avoidable hospital admissions

PENDING

[redacted]

OVERLAP

None.

BATEMAN, D. R.

ACTIVE

P30AF10133 Saykin 07/01/16-06/30/20 0.24 Calendar
Role: Co-Investigator [redacted]
NIA/NIH

Indiana Alzheimer Disease Center: The major goal of this project is to support, carry out and facilitate research on Alzheimer disease and other neurodegenerative dementias as well as serving as a shared research resource.

R01HL128494-01 Clark 05/01/16-10/03/20 1.20 Calendar
Role: Consultant
NHLBI/NIH
APP-ME: Addressing Place & People Micro-Environments in Weight Loss Disparities

This is a randomized trial testing the effectiveness of automated, personalized, and just-in-time weight loss support vs traditional weight loss support.

1R43AG063679-01 (Condon) 04/01/2019-03/31/20 0.30 Calendar
Role: Co-Investigator
NIA/NIH
A Gait and Path Tortuosity System for Monitoring Cognitive Decline from Daily Functions in Individuals with Alzheimer's Disease and/or Alzheimer's Disease Related Dementias (AD/ADRD). Proposed is a sensing system that unobtrusively measures and reports gait properties which are correlated to accepted measures of cognitive decline.

PENDING

OVERLAP
None. If commitment overlap occurs, Dr. Bateman will reduce his effort on all current projects and share responsibilities with other faculty at the Indiana University Center for Aging Research or Indiana University School of Medicine. Dr. Bateman understands that if **is funded, he will not be able to receive any other federal research dollars.**