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: 04/05/2019	FOA: PAS18-187 Clinical Trial:Optional	Council: 08/2019
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 AG063685-01A1	Dual:	Accession Number: 4293604
IPF: 10048406	Organization: CAREBAND, INC.	
Former Number:	Department:	
IRG/SRG: ZRG1 RPHB-Y (12)B	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: ▮▮▮▮	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	Co-Investigator
Todd Sobol M.D.	Optum Complex Care Management	Other (Specify)-Advisor
Shehroz Khan	KITE-Toronto Rehabilitation Instutite	Consultant
Andrea Iaboni M.D.	Univesrity Health Network	Other (Specify)-Advisor
Mohammadreza Faieghi Ph.D	University Health Network	Consultant

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

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

1. TYPE OF SUBMISSION*	**4.a. Federal Identifier**
	AG063685

○ Pre-application ● Application ○ Changed/Corrected Application	**b. Agency Routing Number**

2. DATE SUBMITTED	**Application Identifier**	**c. Previous Grants.gov Tracking Number**

5. APPLICANT INFORMATION   **Organizational DUNS*:** ▮▮▮▮

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

Person to be contacted on matters involving this application
Prefix: First Name*: Adam   Middle Name: Last Name*: Sobol   Suffix:
Position/Title:
Street1*:   ▮▮▮▮
Street2:
City*:   ▮
County:
State*:   ▮
Province:
Country*:   ▮▮▮
ZIP / Postal Code*: ▮▮
Phone Number*: ▮▮   Fax Number: Email: ▮▮▮

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

7. TYPE OF APPLICANT*	R: Small Business

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

8. TYPE OF APPLICATION*	If Revision, mark appropriate box(es).
○ New ● Resubmission	○ A. Increase Award ○ B. Decrease Award ○ C. Increase Duration
○ Renewal ○ Continuation ○ Revision	○ D. Decrease Duration ○ E. Other (specify) :

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

9. NAME OF FEDERAL AGENCY*	**10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER**
National Institutes of Health	TITLE:

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

12. PROPOSED PROJECT	**13. CONGRESSIONAL DISTRICTS OF APPLICANT**
Start Date* Ending Date*	▮
09/01/2019 02/29/2020	

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*: ███████████████

Street2: ███

City*: ████

County:

State*: ███

Province:

Country*: ████████

ZIP / Postal Code*: █████

Phone Number*: █████　　Fax Number:　　Email*: █████████

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15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested* █████████

b. Total Non-Federal Funds* ███

c. Total Federal & Non-Federal Funds* █████████

d. Estimated Program Income* ███

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*: ███████████████

Street2:

City*: ████

County:

State*: ███

Province:

Country*: ████████

ZIP / Postal Code*: █████

Phone Number*: █████　　Fax Number:　　Email*: █████████

Signature of Authorized Representative*	Date Signed*
Adam Sobol	04/05/2019

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20. PRE-APPLICATION　　File Name:

21. COVER LETTER ATTACHMENT　　File Name:

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

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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:

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 agitation 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 near 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:** Determine the feasibility and usability of deployment of CareBand Technology to individuals with ADRD in LTC for a six-week period, and staff recording of observation-based, validated agitation scale data daily. **3:** Explore the relationship between motion variable data, and validated agitation scale data. At the end of Phase I, CareBand will have implemented the CareBand technology in an 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 focus on construction of algorithms informed by any findings of correlation, the ███████ ████████████████████████████████████, and a longitudinal study in multiple long-term care facilities serving individuals with ADRD. Phase II may also include ██████████████████████ 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 decreases caregiver burden.

Narrative

Agitation is one of the most common and distressing neuropsychiatric symptoms (NPS) 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): █████████

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) $100k Winner

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.

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

ORGANIZATIONAL DUNS*: ██████████

Budget Type*: ● Project ○ Subaward/Consortium

Enter name of Organization: CAREBAND, INC.

Start Date*: 09-01-2019   **End Date*:** 02-28-2020   **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			██████	██████	██████

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

Additional Senior Key Persons: File Name: **Total Senior/Key Person**   ██████

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	4.8			██████	██████	██████
1	**Total Number Other Personnel**					**Total Other Personnel**	██████
						Total Salary, Wages and Fringe Benefits (A+B)	██████

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

ORGANIZATIONAL DUNS*: ███████████

Budget Type*:   ● Project   ○ Subaward/Consortium

Organization: CAREBAND, INC.

Start Date*: 09-01-2019   **End Date*:** 02-28-2020   **Budget Period:** 1

C. Equipment Description	
List items and dollar amount for each item exceeding ██████	
Equipment Item	**Funds Requested ($)***
Total funds requested for all equipment listed in the attached file	
	Total Equipment ██
Additional Equipment: File Name:	

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

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**	██

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

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

ORGANIZATIONAL DUNS*: ▮▮▮▮▮▮▮▮

Budget Type*: ● Project ○ Subaward/Consortium

Organization: CAREBAND, INC.

Start Date*: 09-01-2019   **End Date*:** 02-28-2020   **Budget Period:** 1

F. Other Direct Costs	Funds Requested ($)*
1. Materials and Supplies	▮▮▮▮
2. Publication Costs	▮▮▮
3. Consultant Services	▮▮▮
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 (▮▮▮▮) and Tech-Enhanced Life (▮▮▮▮)	▮▮▮▮
Total Other Direct Costs	▮▮▮▮

G. Direct Costs	Funds Requested ($)*
Total Direct Costs (A thru F)	▮▮▮▮

H. Indirect Costs

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

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)	▮▮▮▮

J. Fee	Funds Requested ($)*
	▮▮▮▮

K. Total Costs and Fee	Funds Requested ($)*
	▮▮▮▮

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 ▮

Section B, Other Personnel ▮

Total Number Other Personnel ▮

Total Salary, Wages and Fringe Benefits
(A+B) ▮

Section C, Equipment ▮

Section D, Travel ▮

1. Domestic ▮

2. Foreign ▮

Section E, Participant/Trainee Support
Costs ▮

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other

6. Number of Participants/Trainees

Section F, Other Direct Costs ▮

1. Materials and Supplies

2. Publication Costs

3. Consultant Services

4. ADP/Computer Services

5. Subawards/Consortium/Contractual
Costs

6. Equipment or Facility Rental/User
Fees

7. Alterations and Renovations

8. Other 1

9. Other 2

10. Other 3

Section G, Direct Costs
(A thru F)

Section H, Indirect Costs

Section I, Total Direct and Indirect Costs
(G + H)

Section J, Fee

Section K, Total Costs and Fee (I + J)

Specific Aims

Agitation is one of the most common and distressing neuropsychiatric symptoms (NPS) of Alzheimer's disease and related dementias (ADRD) with close to a quarter of patients with ADRD developing agitation during the course of their illness [1]. Agitation contributes to increased healthcare costs [4], greater caregiver distress [5] and worse quality of life [6]. Differences in agitation reporting can vary according to the time of day, and the person reporting (i.e. family, RN, MD) and can be influenced by recall and other biases. Validated agitation rating scales are time consuming and frequently underutilized by long term care (LTC) facilities. _The problem is_ clinicians, LTC staff and caregivers need a more effective and timely way to objectively monitor agitation.

What remains unknown is whether sensor-based technology can serve as a near real-time, efficient, objective and predictive approach to agitation monitoring. A recent systematic review by Khan et al. [7] examining agitation and aggression in persons with dementia using sensor technology found a positive correlation between actigraphy – a non-invasive measurement of human rest/activity cycles, and agitation. The findings were limited by the small number of trials and participants, short trial duration, and lack of data on user acceptability. Furthermore, it is unclear whether ADRD subjects, 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. If this underline urgent need of improved agitation monitoring is not met, healthcare teams will miss opportunities to intervene early on in medical illnesses that present with agitation (i.e. infections), potentially resulting in a delay in treatment and worse outcomes. And, in the case where there is no clear inciting medical cause, ineffective measurement and treatment of agitation, can result in progression of agitation to a crisis state, leading to emergency department visits, overuse of high-risk psychotropic medications, caregiver exhaustion and injury.

CareBand, Inc., an Illinois-based small business, aims to offer a solution to this need through their iterative, development of an end-to-end wearable technology and near real-time data platform designed specifically for people living with ADRD. CareBand provides near real-time indoor and outdoor precise location, movement, and activity data. The CareBand Technology includes an unobtrusive, wearable design, an infrastructure of small beacons and one gateway per facility and a feature of secure data transfer to a HIPAA-compliant cloud. The technology is passive, always on, and does not require Wi-Fi or traditional cellular technology to send data. _Our long-term goal_ is to demonstrate through an R01 level RCT that CareBand Technology is a viable and useful tool to monitor and predict agitation in ADRD subjects residing in a LTC setting. Then, we would expand the use case for CareBand Technology in bringing to market the developed algorithms to accompany the Technology – which can already be in use for wandering, location, and alerts

The overall objective of this proposal is to engineer and refine CareBand firmware for motion data collection and power efficiency, determine feasibility and usability of CareBand Technology in an ADRD population located in the LTC setting and explore the relationship between agitation and movement variables. _The central hypothesis is_ that CareBand Technology deployment and implementation into a LTC facility utilized by ADRD subjects for a 6 week time period, will result in evidence of feasibility and usability, and that agitation measured during this time period with the Pittsburgh Agitation Scale (PAS) will correlate with heart rate, ADRD subject movement, and intra-room and room-level movement data as captured by CareBand Technology.

To test our central hypothesis and meet the overall study objective we seek to achieve the following:
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: Determine the feasibility and usability of deployment of CareBand Technology to individuals with ADRD in LTC for a six-week period, and staff recording of observation-based, validated agitation scale data daily.
Aim 3: Explore the relationship between motion variable data and validated agitation scale data.

The underline expected outcomes from this Phase I study include a refined cloud logic and power-efficient firmware, feasibility and usability data from the ADRD and LTC staff end users, and evidence of association of agitation with motion variables. This data will be incorporated into the next iteration of CareBand Technology and will provide the foundation for the creation of predictive modeling of incipient agitation that will be tested in either a SBIR Phase 2 or R21 RCT, later to be followed by an R01 size RCT. Based on need and number of LTC facilities in the US, we estimate the addressable market to be ███████.

Research Strategy
(a) Significance | Agitation is a way for a person with dementia to communicate distress or unmet needs, perhaps when speech is no longer a viable manner to do so. Patients who become agitated are more likely to receive high risk psychotropic medications, experience injury, cause injury to others or be removed from the facility; all of which incurs cost and distress. Therefore, measuring it, and ultimately predicting it, would allow for caregivers to comfort and alleviate any relevant stimuli before the situation escalates.

CareBand, Inc, an Illinois-based small business, is developing a wearable technology that tracks real-time indoor and outdoor location and movement. The device tracks individuals up to three miles without using Wi-Fi or cellular data. In addition, the wearable can be programmed to 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 data that can be used to understand behavior and activity and 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 [7, 9–11]. CareBand aims to test data collection with its location and movement 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 [12]. 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" [12]. A recent systematic review by Khan et al. [7] 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, approach to agitation monitoring and predict of future agitation. Furthermore, it is unclear whether ARDRD subjects, 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.

(b) Innovation | This innovative technology uses the unique combination of Bluetooth, GPS, and an internet of things (IoT) communication technology called LoRa to track indoor and outdoor location in real-time. LoRa is important because the system does not use wifi or cellular technology, which many senior care homes do not have. Also, CareBand believes this combination of technology, along with heart rate detection, can be used to monitor and 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 near real-time movement and pattern analysis algorithms has significant potential to enable early detection and changes in behavior and activity. LoRa 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.** LoRa is a great answer for remote battery-powered sensors or devices that communicate over long distances or in remote places. LoRa packages data, which is sent when needed, over long distances 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 LoRa, 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" [13]. CareBand has one patent granted and three additional pending: a utility patent granted on the combination of Bluetooth & GPS for indoor/outdoor tracking for persons with dementia, as well as three patents pending around (1) location, environmental, physiological, and activity data being communicated wirelessly in a hybrid mode, aimed at proactively discerning change in condition, (2) form factor of the device, and (3) a locking clasp that requires two hands to open.

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

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 subject 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. 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" [14]. CareBand is also capable of objectively tracking the effects of a behavioral therapy or drug intervention. **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 presented 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

Figure 2: Current CareBand prototype.

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 thereafter, 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 ████████ from 20 of the most well-known entrepreneurs in Indiana. With that traction, he raised an additional ████████ 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. 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 ████████ 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
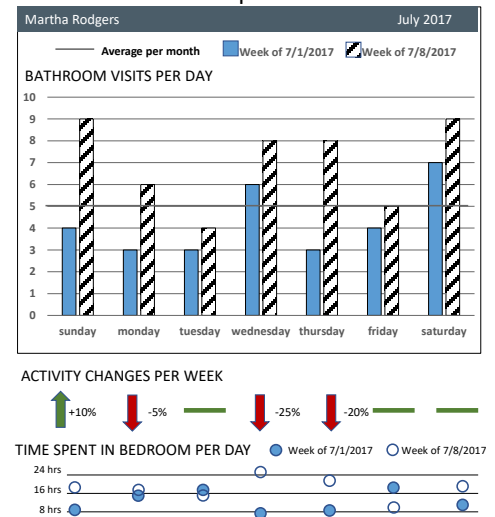
CEO and in 2018, CareBand was featured at the Consumer Electronics Show (CES) and selected as the American Medical Directors Association's (AMDA) 2018 Shark Tank Winner. CareBand began to conduct usability pilots to collect data, first in Bloomington, Indiana and then later at Avanti, a skilled nursing and rehabilitation facility in the northern Chicago suburbs. As a result of early success in these studies, CareBand raised another ████████.

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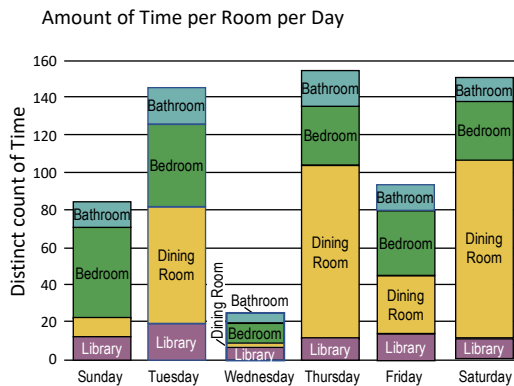

Amount of Time per Room per Day
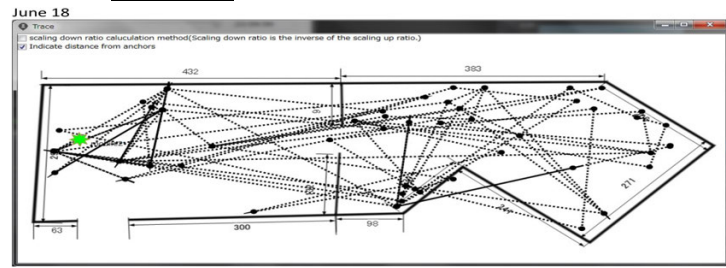
Figure 5: Intra-room pacing raw data.

Early development focused on demonstrating the feasibility of using LoRa 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. ████████████████████████ ██ 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 ADRD subjects 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 co-investigator geriatric psychiatrist & scientist Dan Bateman, MD (site PI for Bethany Village), and machine learning expert Shehroz Khan, PhD, and consultants: Bethany Village Medical Director Ellen Kaehr, MD, geriatric psychiatrist & scientist Andrea Iaboni, MD, DPhil, FRCPC, and post-doctoral student co-supervised by Dr. Khan and Dr. Iaboni, Dr. Reza Faieghi, as well as geriatrician & medical director, 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 to build cloud logic to analyze this granular data for web and mobile applications. H1**: CareBand will reach battery life of 24 hours with granular intra-room location data. The CareBand technology, when collecting room-level indoor data and outdoor GPS data, is charged once every three days for about 30 minutes, through the use of a wireless charging dock. The intent of Aim 1 is to build, test, and upgrade devices with a specific firmware package to enable the collection of accurate and reliable 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 battery life of roughly 8 hours and data transfer every 30 seconds of movement. 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 with each other can be altered. For example, if a facility were to only want to use the nurse call functionality, a firmware package could be constructed and loaded onto the device to accomplish that use case. To accomplish Aim 1, the PI will define the specific requirements of the use case around intra-room location noting items such as the frequency of movement sensed and frequency of data transmitted to the cloud. 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. If moving, the device may send a message to the cloud; if not moving, the device may sleep until a specified time to sense for moving 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 sent to the LoRa network? (2) How often does the device need to join the LoRa 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)? The answers to these questions are important in the firmware delivery. After the PRD is created, the PI will work with OptimalDesign's firmware team to go over the use case requirements. 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. With the final firmware 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 HIPAA-compliant 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. The PI will then 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 intra-room movement and location for end-users.

Aim 1 Milestone, Potential Pitfalls and Alternative Strategies: The milestone for Aim 1 will focus on the development of firmware that works with the existing battery and hardware design to support granular motion data, with a target of 24-hour battery life. The potential pitfall with the firmware is that based on the requirements, the battery life may peak at a number between 8 hours and 24 hours. If this were to happen, the CareBand team would reassess the battery performance and may need a new battery for future research. If this happens, the team will devise a charging strategy to be used during the Phase I study and explore hardware design changes with an enhanced battery in additional iterations in Phase II and beyond. While a battery life of <24 hours is not ideal for staff or ADRD subjects, it will not interfere with the overall goal of Phase I. In this situation, staff would continue to use the CareBand device but charge the device multiple times a day for the study.

Aim 2: **Determine the feasibility and usability of deployment of CareBand Technology to individuals with ADRD in LTC for a six-week period, and staff recording of observation-based, validated agitation scale data daily.** **H1:** CareBand Technology is usable and acceptable for individuals with ADRD and through LTC staff completed observation-based scales and qualitative data. More specifically, the CareBand team will achieve 75% compliance of the stated protocols for 6 weeks of qualitative reporting (including charging protocol and data collection protocol). Overall usability will be measured through responses from focus groups, with at least a 70% acceptance rate across each group. H2: Data will be retrieved, cleaned and organized for handoff to CareBand's partner in data analytics, Dr. Khan and his team, Dr. Faieghi and Dr. Iaboni. This Aim will require three months and is described below: preparation (4 weeks), study (6 weeks), and wrap up (2 weeks). Dr. Daniel Bateman will lead this study at Bethany Village.

Approval: The Bethany Village facility is managed by American Senior Communities and is owned & operated by the Health and Hospital Corporation of Marion County (HHC). As such, HHC must approve research that is done at Bethany Village. We have received IRB approval for a preliminary pilot study and subsequently received approval from Senior Vice President – Long Term Care, Shelia D. Guenin, H.F.A., at HHC. We have also been in close communication with the Executive Director of the facility, Neha Patel HFA, MBA, of American Senior Communities. Both Ms. Guenin and Ms. Patel have submitted letters of support for this study.

Preparation: In conjunction with Bethany Village leadership, the PI will work to educate staff, install hardware, and help Bethany Village prepare 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 LoRa 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 the ADRD subjects and

device details including battery levels. Next, the PI will work with Dr. Bateman, Dr. Kaehr and the Director of Nursing to conduct training sessions for 15 Bethany Village 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 for those residents who require it, charging and charging cadence, administration of the 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 [14]. 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.

Due to the subjective nature of various staff administering the PAS, 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 subjects. The device will collect HR data on an ongoing basis; the PI will extract data collected approximately every 20 days during charging. HR will not be visible to the residents or staff. Next, Dr. Bateman (site-PI, co-I), Dr. Sobol and Dr. Kaehr (Medical Director at Bethany Village) will identify potential ADRD subjects for recruitment into the study. Dr. Ellen Kaehr will use the Brief Interview for Mental Status (BIMS) completed, as a part of the ADRD subjects quarterly Minimum Data Set 3.0, to assess potential ADRD subject's capacity to consent for research[16]. The BIMS helps establish a cognitive baseline, identify ADRD subjects who need further cognitive evaluation and track change in cognition over time. The BIMS allows the CareBand study team to gain insight into the subject'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 potential ADRD subjects 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 ADRD subjects either directly from the participant or from the potential subjects legally authorized representative (LAR).

Study: The study intervention is six weeks duration with a total of 15 ADRD subjects and 15 LTC staff subjects. During the study, each stakeholder will have specific tasks. The staff will have three key tasks to complete. 1) Staff will complete the PAS once daily for 6 weeks for each ADRD subject participating in the study, 2) Staff will record qualitative observations of agitation for participating ADRD subjects daily on a data collection form, and 3) depending on the firmware package from Aim 1, staff will be responsible for charging the device once a day or once every few days. Dr. Bateman and Dr. Kaehr will oversee the staff, check in on the ADRD subject's comfort with the device, and collect PAS and Qualitative feedback sheets. Once a week, Dr. Kaehr will formally meet with the site-PI and the PI with the option of including 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 beacons from each room and hallway as well as the gateway from Bethany Village. The PI will also remove all tablets from nurse's stations and devices from ADRD subjects. Dr. Kaehr will remove the binders and any other materials related to the study from staff.

To measure usability and feasibility for all involved parties, focus group workshops will be held both pre- and post- deployment. They 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). Participating residents and family will each receive a ███ gift card at the conclusion of their focus group session; HHC does not want staff to be compensated. Audio will be recorded and later transcribed by Tech-Enhanced Life. With ADRD subjects, 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 the ADRD subjects, 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].

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

CareBand data, HR data and PAS data. A potential pitfall may be recruitment and retention of ADRD subjects. However, Dr. Kaehr, is familiar with the patient census, and feels confident that the enrollment target is reasonable. Another potential pitfall 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 weekly throughout Aim 2. If a problem arises with the data collection, the research team will do additional staff trainings and be available on site more often during the 6 weeks to ensure the required data is available to complete Aim 3. For the focus groups, the milestone is 70% acceptability for each workshop. This will inform further development and design.

Aim 3: **Explore the relationship between motion variable data and validated agitation scale data**. **H3:** Successful data collection and analysis that shows correlation to measuring agitation. This will eventually result in an agitation index based on data collected that indicates the extent to which somebody is showing signs and symptoms of agitation. The analysis will be driven by the question: can CareBand data accurately detect agitation in subjects with ADRD? More specifically, the PI and Co-I, Dr. Khan, will aim to investigate the hypothesis that agitation is highly correlated with increased subject movement, as measured through staff observations of subject agitation and the PAS and intra-room 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 pending agitation, allowing alerted staff to intervene before the use of psychotropic drugs or hospitalization becomes necessary.

To investigate the hypothesis, the PI, Dr. Khan, Dr. Faieghi, Dr. Iaboni, and Dr. Sobol 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) HR data; 3) PAS data; and 4) qualitative observation data. CareBand believes, in conjunction with the Nokia wristband, its technology can detect agitation-associated heart rate increases and aberrant motor behavior through excessive movement of the wrist/arm, pacing or wandering/exit seeking behavior. Although, CareBand cannot collect verbal aggression data with the proposed use of technology, the team will capture this information with validated agitation scales. The PI, Dr. Khan and Dr. Faieghi 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 day, with an entry in the data for each day-ADRD subject combination. The team will train regression models. The goals are to find correlations between features and the relevant clinical measure, and then to accurately predict the intensity of behavior consistent with the clinical measure. The relevant extracted features will be included as 'dependent' variables. More specifically, the team will extract generic time and frequency domain features from the accelerometer data, along with domain specific features, such as Teager energy that correlates well with agitation data in Dr. Khan's experience. The team will also extract novel features from the location data, such as time spent in the room, time spent at the exit (door), movement across different rooms, etc. All of these features will be included as 'dependent' variables. The independent variable or the ground truth will be derived from the validated assessments. The team will test models using linear regression, polynomial regression, ridge/lasso regression, and more advanced methods as needed. Finally, the PI, Dr. Faieghi, and Dr. Khan 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: The milestone for Aim 3 is to establish the relationship between the various data sources. A potential pitfall could be inconsistent PAS assessments, meaning staff may forget to complete the assessment or may complete them at the wrong time. This may limit the accurate testing of predictive models. To circumvent, the team will employ data imputation techniques, such as expectation maximization. At the end of Aim 3, CareBand will have established statistical relationships between the data sources.

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 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.

Commercialization: Dementia care is a large and growing market. CareBand will initially target sales of the device directly to senior living facilities: Assisted Living & Memory Care with a Market Size of 300,000 and a Market Potential of ███ Skilled Nursing Homes at 450,000 and ████, and Home Healthcare Agencies at 4.5 Million and ███. 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.

1.0 INTRODUCTION

This proposal is a resubmission of an SBIR application submitted by **CareBand, Inc.** in **September 2018**. The application (**AG063685**) received an **Impact Score of 45**. The project team thanks the reviewers for their thoughtful insights and comments. We were encouraged by comments: "The review panel acknowledged the importance of the technology to address an important public health concern…" and noted "… a high level of innovation and strong commercial potential." Reviewers raised a number of concerns.

1.1 <u>Concern over level of innovation</u>

CareBand pinpoints the users' location down to room and floor in a facility, and can get even more granular than that, providing important data that can influence strategies in care. This innovative design has resulted in the filing of several patents and award of one patent thus far in January 2019. Neuropsychiatric symptoms of dementia (NPS) occur in 98% of individuals with AD during the course of their illness and 25% of this population will experience agitation, a subset of NPS [1]. Studies estimate agitation to account for 35% of the direct annual costs for patients with AD [2]. CareBand believes that by using its motion and location data in conjunction to Nokia's Wristband for heart rate data to detect--or even predict episodes of agitation--caregivers and healthcare providers can proactively treat agitation and the underlying medical conditions that may be responsible for the agitation (i.e. infection). If unchecked, agitation may escalate and result in injury, an emergency room visit and/or the use of antipsychotic medications.

1.2 <u>Defining agitation in data terms and measuring agitation today</u>

CareBand will use the International Psychogeriatric Association (IPA) 2015 Consensus Provisional Definition of Agitation in Cognitive Disorders as the primary definition [3]. In practice, agitation in the targeted population is primarily measured through the use of traditional survey based clinical scales. Recently though, Dr. Shehroz Khan and his machine learning team has begun to review and evaluate technology to measure agitation in individuals with dementia. In this Phase I study, CareBand will ask nursing staff to document presence or absence of agitation once every day, not every 8 hours as originally proposed after detailed conversation with Bethany Village staff. This will include completion of the Pittsburgh Agitation Scale (PAS) and qualitative observation data. Although CareBand cannot collect verbal aggression data with the proposed use of technology, the team will capture this information with validated agitation scales and qualitative observation.

1.3 <u>Lack of detail in screening, recruitment, and observation</u>

Recruitment will take place at Bethany Village, a skilled nursing facility in Indianapolis, IN. ADRD subjects will be suggested by medical director and treating physician Dr. Ellen Kaehr, who acts as a consultant to the team. Qualifying participants will be screened by a research assistant (RA) who will, depending on subject capacity as determined by Dr. Kaehr, contact either the legally authorized representative or the ADRD subject. This will be overseen by Dr. Bateman, co-I and site PI. Informed consent and assent will be reviewed with both participants of the dyad and subsequently enrolled. Demographics, information on cognitive disorder diagnosis, medical history and baseline agitation scores will be obtained for each participant. Nursing staff will administer and record the findings of the 1) PAS and 2) Qualitative observations of agitation once every day for the 6-week study. Staff will recharge the device up to every 3 days depending on the achieved power consumption in firmware package.

1.4 <u>Request for additional detail around milestones, analysis, and outcomes</u>

Quantitative measures of success have been identified for each Aim: 1) Reach battery life of 24 hours with granular intra-room location data; 2) Achieve 75% compliance of the stated protocols for 6 weeks of qualitative reporting (including charging protocol and data collection protocol). The other important outcome of this Aim is data retrieved, cleaned and organized for handoff to CareBand's partner in data analytics, Dr. Shehroz Khan; 3) Successful data collection and analysis that shows correlation to measuring agitation. This will eventually result in an agitation index based on data collected that indicates the extent to which somebody is showing signs and symptoms of agitation. Overall usability will be measured through responses from focus groups, with at least a 70% acceptance rate across each group.

1.5 Team Composition

One major change in the revised project plan is the expanded role of dementia expert Dr. Bateman (Indiana University) as Co-Investigator. Additionally, the research team now includes the machine learning expert Dr. Khan (co-I), Dr. Faieghi (consultant), and Dr. Iaboni (consultant) from the Toronto Rehabilitation Institute.

SUBRECIPIENT COMMITMENT FORM

If your institution is participating in the FDP Clearinghouse Pilot, complete sections A and C only. If your institution is <u>not</u> participating in the FDP Clearinghouse Pilot, complete all sections. This form must be approved and signed by your organization's Authorized Organizational Representative (AOR). **Please ensure all applicable documents (Statement of Work, Budget, etc) are included with the request.**

SECTION A: Project Information

Subrecipient Legal Name:_____ Subrecipient PI:_____

Subrecipient Central Email: ███████_____ Subrecipient Admin. Contact Email: ███████_____

Direct Costs: ██████_____ Indirect Costs: ██████_____ Total Costs: $██████_____

Project Title: _____

Period of Performance:_____to _____

Subrecipient's Research Includes (check as applicable):   Human Subjects   Animals   Biosafety   None

If applicable, does your organization certify that it will follow the NIH single IRB plan developed for this project?   Yes   No

Perfomance Address: ████████████   Subaward Type: Cost Reimbursement
                                                                 Fixed Price

SECTION B: Subrecipient's Institutional Information

DUNS #:   EIN: Congressional District:

1.   Yes   No   N/A   Is your organization or PI and/or employees on this project presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in any federal department or agency or delinquent on repayment of any federal debt including direct and guaranteed loans and other debt as defined in Uniform Guidance?

2.   Yes   No   N/A   If application is to a federal or federal pass-through sponsor, have any lobbying activities been or will any be conducted regarding this proposal?

3.   Yes   No   N/A   If applicable, does your organization certify that it currently has a PHS-compliant Financial Conflict of Interest (FCOI) policy and a PHS Financial Disclosure for each of the Subrecipient's key personnel?

4.   Yes   No   Does your organization have a federally negotiated F&A rate? If yes, please provide a copy of your F&A rate agreement.

5.   Yes   No   Does your organization receive a single audit in accordance with Uniform Guidance §200.514 (formerly A-133)? If no, please provide a contact and email address below. Name:_____   Email:_____

SECTION C: Subrecipient's Authorized Official Representative (AOR) Approval

I certify that the information provided is true and correct. I am the authorized official representative (AOR) of the Subrecipient named herein, and I have the authority to legally bind my organization in grants administration matters. I understand that: (a) any work we begin and/or expenses we incur related to our proposal prior to full execution of a subaward agreement will be at my organization's own risk. The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

████████████_____   _____

Subrecipient's Authorized Official   Date:
Name:

30th March 2019

CareBand

████████████████████████████████

██████████████

Re: CareBand: Wearable Technology for People with Dementia

Dear Mr. Sobol,

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

Dr. Shehroz Khan will work on and oversee the training of regression models. His goals are to find correlation between features and the relevant clinical measure, and then to accurately predict the intensity of behavior consistent with the clinical measure. The relevant extracted features will be included as 'dependent' variables. This grant is a resubmission of a previous application that was scored last time. Dr. Khan's contribution is intended to help remedy one of the feedback points. Also, Phase I milestones were somewhat under-described, and there is a need for additional methodological expertise in analyzing and interpreting the data.

Dr. Khan possesses a strong background in Machine Learning and its application to health problems. He is currently leading an ongoing study at Toronto Rehabilitation Institute, Canada on using multi-modal sensor network for detecting agitation and aggression in people living with dementia. He has extensive experience in predictive modeling, feature extraction and model evaluation.

Sincerely,

████████████████████

Name: Dr. Shehroz Khan
Title: Scientist, KITE - Toronto Rehabilitation Institute,
     University Health Network,
     Canada

Contact information: ████████████████████████████████████
Email: ████████████████████
Phone: ████████████████████

April 1, 2019

Mr. Adam Sobol
CareBand

Dear Mr. Sobol,

Re: CareBand - Wearable Technology for People with Dementia

I am writing to offer my support as a consultant for the SBIR application entitled "CareBand: Wearable Technology for People with Dementia".

I am an Assistant Professor in psychiatry at the University of Toronto, a geriatric psychiatrist and clinician-researcher at the University Health Network in Toronto, Canada, with a research focus on the use of sensors for monitoring health status and behavioural symptoms in people with dementia living in nursing homes. I have expertise in the design of clinical studies of dementia technology, and my research team includes computer scientists and biomedical engineers who are developing statistical and machine learning models for analyzing longitudinal sensor data.

I first developed an interest in your technology in September 2018, while looking into sensors for real-time location data collection in the nursing home environment, and I enjoyed the opportunity to observe your technology in action in a visit to your testing site in November 2018. I see a lot of promise for this technology in addressing the feasibility of behavioural and health status monitoring in nursing home settings, and the clinical value of the CareBand technology in daily dementia care.

During Phase I, as a consultant for this project, I will contribute my expertise in clinical study design, to help develop the study protocol. I will also co-supervise Reza Faieghi, a biomechanical engineer and post-doctoral researcher who will assist with the data processing and labelling, as well as the methods for machine learning. In that role, I will provide input into the feature analysis and modelling in Phase II.

I very much look forward to working with you on this project.

Sincerely,

Andrea Iaboni, MD DPhil FRCPC
Geriatric Psychiatrist and Clinician-Researcher

April 3, 2019

Mr. Adam Sobol
CareBand, Inc
████████████████████
████████████████

Dear Mr. Sobol,

I am writing in support of CareBand's SBIR resubmission entitled, "CareBand: Wearable Technology for People with Dementia." I am excited to see that CareBand received an impact score of 45 on their initial SBIR proposal and look forward to taking a more active role in CareBand's proposed resubmission as a Co-Investigator and Site-PI, rather than consultant.

As a clinician scientist at the Indiana University Center for Aging Research and Regenstrief Institute, Co-I of the Indiana Alzheimer's Disease Center and practicing geriatric psychiatrist, I am committed to the study, design and implementation of novel, effective interventions to assess and treat neuropsychiatric symptoms (NPS) of dementia. I believe CareBand technology has great potential as a novel, NPS monitoring device capable of improving the care and quality of life of people living with dementia (PWD).

As you know, I have worked closely with CareBand, Inc., the Bethany Village Team made up of Medical Director Ellen Kaehr, MD and Executive Director Neha Patel, and the Health and Hospital Corporation – American Senior Communities Long Term Care (HHC-ASC LTC) Research Committee to develop a human subjects research pilot study protocol that is acceptable to all stake holders. The pilot study protocol has been approved both by the Indiana University Institutional Review Board and the HHC-ASC LTC Research Committee. The pilot assesses the feasibility and usability of CareBand from the viewpoints of PWD and LTC staff, and explores the relationship between observed agitation in PWD and CareBand motion data. Although, pilot data is not available at the time of this resubmission, we expect the study to commence shortly and to be able to share this data if given the opportunity to respond to reviewers. Of note, the approved pilot protocol is identical to the protocol proposed for this SBIR with the exception of intervention duration (2 weeks - pilot vs. 6 weeks - resubmission), therefore we expect to receive full approval of the proposed SBIR protocol.

If funded, my responsibility as Co-I will be to oversee the Regenstrief Institute Research Specialist in their responsibilities of study implementation, subject recruitment, completion of informed consent, maintenance of databases and compliance with research protocols.

I have great confidence in CareBand and our team's ability carry out the proposed study.

Sincerely,

████████████████████

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

March 26, 2019

CareBand

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███████████████

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 $25,000. 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.

Our team shared CareBand's excitement in scoring last year and look forward to working with Mr. Adam Sobol and other collaborators on this project to enhance the quality of life for patients through proactive technology.

Sincerely,

JD Sims

OptimalDesign

Business Development Manager

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████████████████
████████████████████

Tech-enhanced Life

March 21, 2019

Mr. Adam Sobol
CareBand
██████████████████████████████
█████████████████

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 ██████, with an additional ██████
allocated for travel expenses. The total fee for service is ██████

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. We are
excited you got scored in the last round. We would definitely be enthusiastic to
collaborate if you get the grant this time around.

Sincerely,

Dr. Richard G. Caro
CEO, Tech-enhanced Life
██████████████████████████

Indiana University Health

March 24, 2019

To whom it may concern:

The IU Health Alzheimer's Resource Service (ARS) is writing this letter in support of CareBand. We want to thank you for taking the time to review the support letter that we (and others) sent last year, and for scoring Careband at that time. We hope that you consider them carefully this year as a recipient of funds.

We have watched this company and their product grow and strengthen over the last several years, and can say with certainty that it is a product that will change the lives of many people who are living with dementia by allowing them some measure of independence, promoting their safety and providing their family and care partners peace of mind.

By tracking movement and alerting families when a situation may need attention, Careband also reduces the risk of isolation that can occur when a dementia diagnosis is given. Their product can be used both in and outside of facilities to unobtrusively monitor individual patterns and alert facility employees or engaged family members to potential needs before they become emergent. Careband offers a service that is not currently available in most communities and could contribute to prolonged independence in the community, quicker emergency response times, root cause analysis for repetitive or unwanted behaviors, and so much more.

The ARS has had a continued partnership with Adam and the Careband team since its inception. We have been very pleased with the professionalism and caring nature of the Careband team as they have gathered information and developed their product to work for real people. We believe that this is a product that many of our clients will jump at the chance to purchase when available and we are often asked when it will hit the market.

As a service that seeks to connect our clients with support and resources to improve their quality of life, we are excited to help them make connections with Careband and feel that there should be continued support for the development and release of this product in the future.

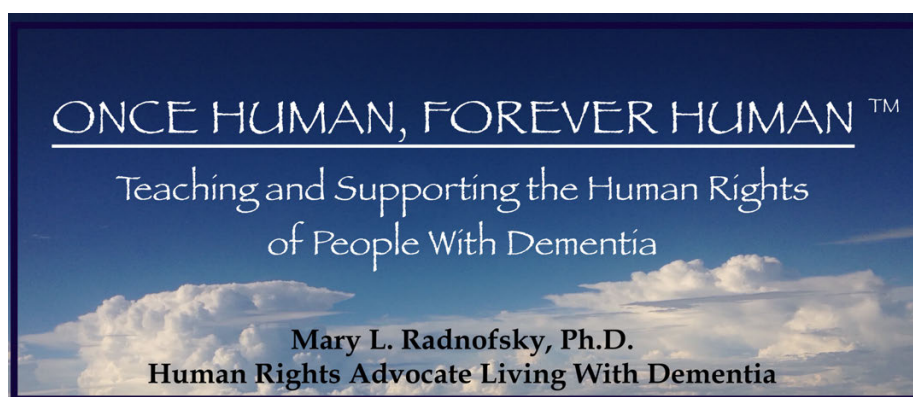Thank you so much for your consideration,
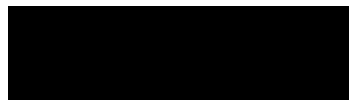
Dayna Thompson MS, EdS, LMHC
Alzheimer's Educator
IU Health Bloomington – Alzheimer's Resource Service
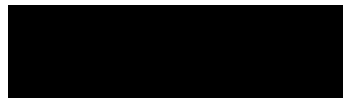
Amanda Mosier CDP, CDCM, SSD, CADDCT
Community Health Coordinator
IU Health – Alzheimer's Resource Service

March 27, 2019

CareBand

██████████████████████████████

████████████

I'm happy to fully and unconditionally recommend CareBand as a support mechanism to people with dementia, for the immediate purposes of identifying changing levels of anxious behaviors, monitoring location, movement, and other physiological functions, so as to ultimately improve their wellbeing.

As a person living independently with younger-onset dementia for 14 years, I believe CareBand would be a good backup system for me. It would provide a doctor, and/or family member of information in case of emergency, without otherwise intruding on other aspects of my life.

I trust Adam Sobol's integrity as he and his team expand CareBand to identify medical and social needs for those of us who may be unable to ask for help when we have aphasia, stroke, blackouts, or are in unsafe conditions – which can leave disabled people at an inherently unfair and inhumane disadvantage for survival.

I believe CareBand would thus help provide equality for people with disabilities under stressful, anxious, or fearful circumstances, giving us a better chance to survive, and even thrive again.

Mary L. Radnofsky, Ph.D.
Advocate for the Human Rights of People with Disabilities

Dementia Action Alliance
Powered by People with Purpose
Dementia, including Alzheimer's

August 23, 2018

Mr. Adam Sobol, Founder & CEO
CareBand
██████████████████
████████

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, M.Ed.   ██████████████████
Board Chair, Dementia Action Alliance   ████████

Dementia Action Alliance ♦ ████████████████████

References

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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 ██████████ and is a member of MATTER, a healthcare startup incubator operating out of ██████████████████████████. 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. As a member of MATTER, CareBand 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.

CareBand's dedicated office space is located at MATTER (████████). MATTER occupies 25,000 square feet in ██████████████████████. 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.

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.

Bethany Village, an American Senior Communities Facility
Bethany Village is a 100-licensed bed skilled nursing facility on the ██████████████████. 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 disease neuropsychiatric symptom care expert Teepa Snow.

American Senior Communities (ASC)
ASC provides senior healthcare and rehabilitation services in Indiana. The company offers program to restore abilities lost due to stroke, cardiovascular difficulties, orthopedic surgery, and other debilitating conditions; and Alzheimer's disease and other dementia patient care services. Provision of services include long term and nursing care, respite, hospice care, garden homes, assisted living apartments, and energy wellness services. American Senior Communities, LLC was founded in 2000 and is based in ██████████████. ASC manages over 80 different facilities throughout the state of Indiana.

Health & Hospital Corporation of Marion County (HHC)
HHC operates the Marion County Public Health Department, Eskenazi Health, Eskenazi Health Foundation, Indianapolis EMS and Long Term Care. HHC is the licensed owner and operator of Bethany Village and a number of other facilities. ASC is contracted to manage the day to day operations and activities of 78 different HHC facility locations.

Indiana University – Overview
Indiana University Purdue University Indianapolis (IUPUI) is located in ██████████████████. IUPUI is home to 20 schools from both Indiana and Purdue universities: Medicine, Dentistry, Health & Rehabilitation Sciences, Nursing, Science, Engineering & Technology and Informatics and Computing among them. As the state's premiere site for training in the health care professions, the health and life sciences are central to the mission of IUPUI. The Battelle Memorial Institute ranked Indiana as being among the top four in the nation as defined by numbers and concentrations of bioscience jobs. Indiana is home to more than 300 life science manufacturing firms, more than 200 biotechnology or physical science research laboratories, and nearly 1,100 life science product wholesalers.

Indiana University Center for Aging Research (IUCAR)
IUCAR was established in 1997 with a vision to improve the quality of life of older adults through interdisciplinary health care research. The Center was founded through a combination of funding from Indiana

University and the Regenstrief Institute, Inc. Dr. Christopher Callahan leads IUCAR as the founding director. There are currently 14 researchers (MD and PhD), including Dr. Bateman, whose primary academic mission is within this center. Faculty members have expertise in geriatrics, gerontology, health services research, clinical epidemiology, behavioral economics, survey research, clinical trials, sociology, biostatistics, health education, rehabilitation, health promotion, mobile health technology, and disease management. All current faculty members have active extramural funding from the National Institute of Health, DHHS, the VA, private foundations, and/or industry. The primary research themes of IUCAR include aging brain illnesses (Alzheimer's disease, dementia, depression, delirium, and stroke), self-management of chronic conditions, and new models of health care delivery for older adults (with special emphasis on care management and information technology).

In addition to the core IUCAR faculty, we collaborate with over 25 "Affiliated Scientists" representing a broad range of academic disciplines. The majority of these scientists are employees of the IU School of Medicine, Nursing, Public Health, and Health and Rehabilitation Sciences, but other Schools and Programs are also represented. We have established a Community Advisory Board to inform us on the health care concerns of our local community and to provide us with feedback on problems related to research among older adults. IUCAR, its faculty and staff are stationed within the Regenstrief Institute, Inc. on the campus of the IU School of Medicine. IUCAR is one of the three main research centers supported by the Regenstrief Institute, Inc. (the other two programs are health services research and biomedical informatics).

IUCAR faculty have access to a strong foundation of research support, including office space in the Regenstrief Institute, Inc. The center is comprised of staff, administrative assistants, program managers, budget specialists, masters-level biostatisticians, and research assistants. Each investigator is provided with a personal computer suitable for their work, as well as, information technology support.

Regenstrief Institute, Inc.
Sam Regenstrief, an Indiana industrialist, founded the Regenstrief Foundation in 1969 to support investigations and improvements in health care delivery. In 2002, the Regenstrief Institute, Inc. became a freestanding, not-for-profit research institute. The Regenstrief Foundation, now established as a grant-maker in health, provides a core operating budget to the Regenstrief Foundation in the amount of ▮▮▮▮▮▮▮. In October 2016, Peter J. Embri, MD, an internationally renowned expert in biomedical informatics, took over as president and CEO of the Regenstrief Institute, Inc. The Institute's annual budget of approximately ▮▮▮▮▮▮ is largely earned from federal grants and contracts focused on research. The Institute is made up of three core research centers in (1) biomedical informatics, (2) aging research (IUCAR), and (3) health services research. The Regenstrief Institute is one of the largest not-for-profit research organizations in ▮▮▮▮▮, affiliated with IU school of medicine and Eskenazi Health. Most of the early research conducted by Regenstrief investigators involved participants from Eskenazi Health (formerly Wishard Hospital) one of the largest safety-net health care sysems in the nation. Because of its strong relationship with the IU school of Medicine and Eskenazi Health, there has been a great degree of collaboration among IU physicians and Regenstrief investigators. Over the past 20 years, the patient-based clinical research has expanded to a laboratory that approximates the entire Indianapolis community. The research milieu within the Institute extends access to other faculty investigators with a team of interdisciplinary health services research expertise including gerontology, medical sociology, social science, epidemiology, biostatistics, health economics, computer science, medical informatics, medical outcomes, and implementation research.

Indiana University School of Medicine
The Indiana University School of Medicine (IUSM) is the only allopathic medical school in the state of Indiana. The school is one of the largest medical schools in the country with more than 350 students per class. There are nine medical campuses across Indiana: Indianapolis, Bloomington, Evansville, Fort Wayne, Gary, West Lafayette, Muncie, South Bend and Terre Haute. The majority of physicians in Indiana trained as students and/or residents at the IU School of Medicine. In 2018, the US News and World Report ranked IU School of Medicine as 41st in research funding. Training programs for interns, residents, and fellows cover over 90 medical and surgical specialties, including geriatric psychiatry. The Indianapolis campus includes five main hospitals including Methodist Hospital, University Hospital, Eskenazi Health, Riley Hospital, and the VA Hospital. IUSM offers a statewide resources and reach for investigators.

Indiana Alzheimer Disease Center (IADC)
Dr. Bateman is a Co-Investigator for the IADC Outreach and Recruitment Core, and contributes to the IADC Clinical Core. The IADC was originally funded by the National Institute on Aging (NIA) in 1991. In 2004, the IADC competitively applied for and received funding for a Data Management and Statistics Core. The focus of the IADC is on subjective cognitive impairment, behavioral neurology, clinicopathological correlations, biochemistry, and genetics of AD, frontotemporal dementia and Parkinsonism linked to chromosome 17 (FTDP-17), Gerstmann-Sträussler-Scheinker disease (GSS), Parkinson disease and other hereditary diseases associated with abnormal protein accumulation. The IADC has collaborated with IUCAR researchers on several clinical trials and longitudinal cohort studies focusing on Alzheimer's disease and related conditions.

The IADC includes patient services, family services, research, education, and training for Alzheimer's disease and related dementias (ADRD). Patient and family services include home visits, assessments, bereavement and grief counseling. Research includes drug trials, brain imaging studies, family caregiver research, and a cross-cultural epidemiological study with the University of Manitoba and the University of Kenya. Both medical and allied health professionals train in this center.

Department of Psychiatry, Indiana University School of Medicine and Indiana University Health
Dr. Bateman, is an assistant professor in the IUSM Department of Psychiatry. The Department of Psychiatry is made up of more than 75 core faculty members (including psychiatrists, psychologists, and scientists). It is located at the recently built, state of the art IU Health Neuroscience center, also called Goodman Hall. The department is dedicated to neuroscience clinical services, basic science research, clinical research, and education. The IU Health Neuroscience center combines ambulatory services and imaging facilities into one space so that patients can receive "one-stop shop" type care enhancing the quality of care in an expedited fashion. The IU Health Neuroscience center is also adjacent to Methodist Hospital and close to University Hospital and Eskenazi Health where the department provides inpatient services. In addition, it houses the NIA-funded Indiana Alzheimer's Disease Center, a nationally recognized resource and leader in Alzheimer's disease and neurodegenerative disorders. The setting of the department is thus designed to maximize clinical service, education, and research.

Division of Geriatrics, Department of Medicine, Indiana University School of Medicine
Dr. Kaehr is a geriatrician at IUSM. The department has a partnership with both IU School of Medicine and IU Health. The division of geriatrics and the department of medicine focus strongly on clinical service, teaching and research. The department of medicine has over 130 faculty members and an annual budget of ▮▮▮ The division of geriatrics is led by director, Cathy Shubert, MD. The division has been designated as a John A. Hartford Foundation Center of Excellence in Academic Geriatrics. The division provides care in the outpatient clinic for senior health, in the inpatient Acute Care for Elders (ACE) geriatric service, in a home visit program, as well as in many nursing homes in Indiana. With the partnership with IUSM, the division has many affiliated hospitals on the main IUSM campus including Eskenazi Health, the Roudebush VA Medical Center, and Methodist Hospital. Eskenazi Health remains the flagship system for the IU geriatrics program in terms of inpatient and outpatient clinical services, house-staff education and research activities.