



Sample Application for Small Business Funding

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<https://www.nia.nih.gov/research/sbir/nia-small-business-sample-applications>

SUMMARY STATEMENT

PROGRAM CONTACT:

(Privileged Communication)

Release Date: 12/14/2018

Revised Date:



Application Number: 1 R43 AG063685-01

Principal Investigator

SOBOL, ADAM

Applicant Organization: CAREBAND, INC.

Review Group: ZRG1 RPHB-Y (13)
Center for Scientific Review Special Emphasis Panel
Small Business: Psycho/Neuropathology, Lifespan Development, and STEM Education

Meeting Date: 12/06/2018
Council: JAN 2019
Requested Start: 04/01/2019

RFA/PA: PAS18-187
PCC: 2BCOGDP

Project Title: CareBand: Wearable Technology for People with Dementia

SRG Action: Impact Score:45
Next Steps: Visit https://grants.nih.gov/grants/next_steps.htm
Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Children: 3A-No children included, scientifically acceptable

Project
Year
1

Direct Costs
Requested

Estimated
Total Cost

TOTAL

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

BUDGET MODIFICATIONS

1R43AG063685-01 Sobol, Adam

COMMITTEE BUDGET RECOMMENDATIONS

RESUME AND SUMMARY OF DISCUSSION: This Phase I SBIR application proposes to develop CareBand, a technology designed to assess agitation expressed by people with dementia who reside in a residential care environment. The review panel acknowledged the importance of the technology to address an important public health concern, agreeing that if successful, the CareBand wireless sensor could provide a real-time alert to care staff of impending agitation. The scientific premise is based on the association between agitation and movement behavior, and the investigative team, led by Dr. Sobol, has the expertise to develop the prototype and determine its feasibility. The review panel also noted a high level of innovation and strong commercial potential. Along with these strengths, however, reviewers also noted some weaknesses that tempered their enthusiasm for the project's overall impact. While agitation is associated with movement behavior, there are certain expressions of agitation that may not be captured by the wrist-band sensor. The development and testing protocol are not fully described, and the application does not sufficiently discuss issues such as power consumption, quantitative behavioral or agitation outcomes. Phase I milestones are somewhat under-described, and there is a need for additional methodological expertise in analyzing and interpreting the data. At the end of the discussion, the panel reached consensus that this is a well-devised application with strong commercial potential; however, the strengths only moderately outweigh the weaknesses, leading to a predicted impact in the area of behavioral agitation among people with dementia in the moderate range.

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

[REDACTED], and a longitudinal study in multiple long-term care facilities serving individuals with ADRD.

[REDACTED]. A significant market opportunity exists for the CareBand technology in alerting caregivers to early signs of agitated behavior in people living with dementia, allowing

caregivers to intervene before the need for psychotropic medication or hospitalization. This preemptive intervention enhances quality of life for individuals living ADRD and it decreases burden on caregivers.

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

CRITIQUE 1

Significance: 2

Investigator(s): 3

Innovation: 2

Approach: 4

Environment: 3

Overall Impact: Applicant proposes to develop CareBand, a wearable technology and real-time data for individuals with Alzheimer's disease and related dementia (ADRD), with the goal of determining the level of agitation. This is an important issue for ADRD patients, as constant monitoring and early detection of agitation may help nursing staff and caregivers to take better care of patients before symptoms increase, which could improve patient outcomes. The scientific premise is strong, and PI has already developed a prototype with some preliminary data on the device capabilities. The team is well qualified, although PI has limited research experience, but consultants bring required clinical expertise. The product seems innovative with the application of an IOT (Internet Of Things) network and wearable motion detection as measure of agitation. The scientific rigor is reasonable with a logic project plan, methods, and evaluation, but the system development and testing are not fully described. The product may have a high commercial potential with application in nursing homes, memory care, and assisted living facilities, as a new tool to assist caregivers to determine patient (agitation) symptoms. Detracting from these strengths, the enthusiasm is reduced by the lack of clarity on existing solutions for measuring agitation, fragmented project team, and concerns on the viability of the system due to power consumption/battery life issues. Study reproducibility is also problematic because of the lack of enough information on quantifiable outcomes.

1. Significance:

Strengths

- Agitation is very common in dementia, and it is a very distressing symptom for patients.
- The scientific premise is well established with citations and rationale regarding the need for better determination of agitation levels in dementia patients, in addition to past studies on agitation and activity correlation.
- Research may advance the field with better understanding and correlation between agitation and sensor data (patient movement).
- If product is successful, product may help to identify early signs of agitation and alert caring staff to take pre-emptive measures.
- There is a commercial potential for skilled nursing homes, memory care, and assisted living facilities.

Weaknesses

- There is insufficient description on existing solutions and approaches.

2. Investigator(s):

Strengths

- PI has background in software engineering and cybersecurity and has patent applications for wireless devices and systems for tracking patients.
- Professors from Indiana University School of Medicine will provide clinical expertise.
- Consultants will assist with firmware, hardware development, and other technical tasks.
- The overall team seems well qualified for the project, with expertise in nursing, geriatrics, and Alzheimer's Disease.

Weaknesses

- PI does not have past research support.

3. Innovation:

Strengths

- The application of LoRaWan and Internet of Things (IoT) in a device to determine agitation seems innovative.

Weaknesses

- Although the application covers tracking features, there is little discussion on existing agitation measures.

4. Approach:

Strengths

- PI has developed a prototype of the CareBand device.
- Preliminary results show device capability to track location and movement in a particular area (room/nursing home).
- Research plan is well designed and includes the development of granular motion data collection and tests with end users, in order to determine usability, and evaluate agitation detection.
- The scientific rigor is reasonable. Although brief, the application outlines methods, collected data, and analysis.

Weaknesses

- Poor battery life may affect system performance.
- The development of the system is not fully described appropriately.
- Quantifiable outcomes are not addressed with sufficient details.

5. Environment:

Strengths

- Facilities and resources are appropriate.
- Participation of a skilled nursing facility (Bethany Village).

Weaknesses

- It is unclear if project will need hardware development and testing resources.

Study Timeline:

Strengths

- None noted.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Human Subject Protection plan appears appropriate.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- Inclusion of Women and Minorities is based on demographics of study location. Children are excluded as this is a study for ADRD patients.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 4
Investigator(s): 3
Innovation: 3
Approach: 6
Environment: 2

Overall Impact: This Phase I SBIR application proposes to develop a wearable technology designed to assess agitated behavior among older adults with Alzheimer's disease and related dementias (ADRD) who live in long-term care facilities. The technology addresses the significant challenge in detecting and managing the agitation and aggression problems manifested in people living with symptoms of ADRD. If successful, the proposed technology would be of high healthcare value in surveilling agitation and alerting caregivers and healthcare providers for timely and needed interventions. The scientific premise of the application is based on evidence of the correlation between incidences of agitation and movement behaviors observed in people living with dementia. While innovative in both concept and methodologies, it is uncertain whether the envisioned technology will yield major scientific advances in the field of geriatric care. Major to moderate weaknesses are noted in the significance and approach, and these factors diminish enthusiasm for the application. The project's significance is lowered by the lack of well-defined and quantifiable outcomes on agitation, and by the lack of any strong indication of the success of the proposed device in capturing the intended behavior in the target population. The overall research strategy is developed without rigorous and clearly articulated approaches that would help to establish the initial feasibility of the project and validation of the envisioned product. Given these factors, the overall impact on the field of this proposed application is expected to be in the low to medium range.

1. Significance:

Strengths

- Effective and innovative technologies are needed to monitor agitated and aggressive behavior in individuals with ADRD and alert caregivers. If appropriately developed, these technologies will help decrease the risk to injury to both individuals with ADRD and their caregivers.
- The scientific premise for the project is based on the current literature, which indicates that there is an association between agitation and movement behavior in people with ADRD.
- The commercial potential for the proposed technology may be high, since close to one-quarter of individuals with ADRD develop agitation and aggression throughout the course of their illness.

Weaknesses

- The significance of the application is diminished by the lack of clearly defined and operationalized behaviors resulting from agitation and/or aggression manifested in people with ADRD.
- The significance is further reduced in that there are no clearly quantifiable outcomes described for each of the three study aims.
- The evidence that the envisioned device will effectively capture a wide range of agitated behaviors commonly seen among people with ADRD is not compelling.
- Enthusiasm for the application is reduced in that there is no appropriate strategy developed to quantitatively evaluate the expected outcomes in Aim 3.

2. Investigator(s):

Strengths

- The PI, Mr. Adam Sobol, has demonstrated expertise in software engineering and wireless technologies.
- The three consultants on the team show experience and expertise in the areas of geriatrics and psychiatry.

Weaknesses

- The team does not appear to have significant expertise in analyzing and interpreting the data collected (Aim 3 in particular).
- The team would be strengthened if individuals with expertise in the areas of firmware and hardware development and research design and methodologies were added.

3. Innovation:

Strengths

- The proposed use of the technology to address the risk of wandering by the ADRD population in the context of nursing and long-term care facilities is conceptually novel.
- The approach of combining various communication technologies to track activities in various settings is novel.

Weaknesses

- Although there are elements of innovation in concept and methodology, there is some uncertainty as to whether the project is capable of generating a first-in-class technology that is different from other existing movement tracking devices on the market. It is also uncertain whether the project would yield significant advances in tracking high-risk behavioral activities in the ADRD population and alerting caregivers to these activities.

4. Approach:

Strengths

- Early work that shows the feasibility of using the proposed technology to track location and movement.
- Consideration of potential pitfalls and alternative strategies.

Weaknesses

- The research strategy related to each of the three Specific Aims is not clearly articulated.
- Agitation encompasses a range of activities. In this regard, the type of agitated behavior the envisioned system is intended to capture is not clearly described.
- There is not a clearly developed protocol that describes how subjects will be screened, recruited, and tested (observed). This aspect of Aim 2 lacks scientific rigor.
- There are some extensive monitoring and tracking activities planned in Aim 2. The feasibility of the plan, however, is not established. It is unclear why an 8-hour observation shift will be needed. No justification is provided. It is also unclear where the motion data will be stored and how the data and other survey data from multiple reporting agencies will be recorded, analyzed, and used to guide the evaluation in Aim 3.
- The scientific rigor of the project is reduced in that there is a lack of a specific strategy and quantifiable milestones for evaluating and testing the hypothesis in Aim 3, which is expected to provide initial feasibility and validation of the proposed device.
- Given the underdeveloped plan for data processing and analyses, the proposed timeline may present challenges for the proposed project milestones.

5. Environment:

Strengths

- The environment at CareBand seems adequate for the development and evaluation of the proposed system.
- The letter of support suggests that sources for subject recruitment are adequate.

Weaknesses

- None noted.

Study Timeline:

Strengths

- The study does not involve a clinical trial.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- No concerns.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- The inclusion plans are adequately developed.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 2
Investigator(s): 2
Innovation: 2
Approach: 5
Environment: 4

Overall Impact: Positives include a strong Commercialization Plan, lots of training and business plan development, prior technical testing and data collection, good industry and clinical connections, solid consulting team. Impact is expected to be reasonably high. Negatives include few noted ideas for sophisticated data analysis and a heavy reliance upon outsourcing and third-party solutions for engineering efforts. Overall, this feels like a moderate risk, high reward proposal.

1. Significance:

Strengths

- Addresses agitation classification in Dementia – a significant issue.
- Relatively few companies and researchers focus on this area compared to other areas like ADLs through “smart” devices.
- Also provides a basic system for bed to bath transitions to detect UTI issues.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- Technical background
- Strong connections with medical community.
- Training in startups, commercialization efforts, leading outsourced development projects.

Weaknesses

- Needs to bring internal expertise in data analytics to prosecute a data-driven technology program.
- Not as well trained on research programs themselves, using consultants to cover this limitation.

3. Innovation:

Strengths

- Integration of new radio technologies for localization, both indoors and outdoors
- Addressing shortcoming of clinical metrics in agitation
- Devices well designed for target market

Weaknesses

- Light on data analysis and how the resulting data set will be associated with categories of agitation. Yes, there's a discussion of statistical correlation, but there's more options available if that fails. It is just a simple approach and a fallback plan needs to be in place.

4. Approach:

Strengths

- LoRaWAN provides a much longer-range solution than older wireless technologies.
- Physical device addresses compliance issues with wearable devices.
- Well evaluated hardware and basic data collection – well prepared for a Phase I evaluation in a real-world environment.
- [REDACTED]
- Good connection with established facility and solid plan for trials, including clinicians, training, on-site evaluation, legal issues, and device management for users (RFID for alarm cancelations, tablet for notifications onsite).
- Good commercial partners to stage company in Phase II trials and commercialization trajectory.

Weaknesses

- Little mention or discussion of likely future work on agitation modeling – data will be relatively complex and need more data analysis than the current team has. Likely should be a notable addition to the Phase II of the project.
- [REDACTED]
- No mention of HIPPA compliance in data storage and analysis.
- No formal work or description of what “agitation” will be in data terms. Needs to work with clinicians and data engineers/AI researchers to formalize this definition and the features being collected from their data sources. *entirely doable*, but just not done in this proposal.

5. Environment:

Strengths

- Existing equipment to work with for trials on hand.
- Established relationship with patient trial facility.
- Good connections with third party developers.
- Participation in MATTER incubator and other startup support systems – the proposal reflects a strong likely commercialization trajectory and related impacts.

Weaknesses

- Relying heavily on third party development – company outsources nearly all development, though the PI runs most of the hands-on business dev and clinical work themselves – This can lead to not having a long term technical view of the product development and especially the data analysis in some cases (it is a risk, not a guarantee).

Study Timeline:

Strengths

- None noted.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Working with clinical facility to support IRB requirements.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

- Did not specifically mention HIPPA data protections.

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- has properly analyzed likely inclusion criteria for 55+ age group in trial facility

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

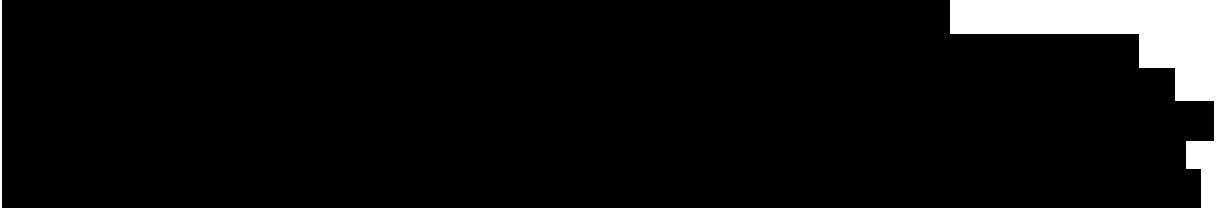
Not Applicable (No Biohazards)

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Budget Modifications Recommended (in amount/time)

- 

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION OF CHILDREN PLAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS:

Reviewers noted a high amount of the budget designated to consultant costs.

Footnotes for 1 R43 AG063685-01; PI Name: Sobol, Adam

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html>. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

The roster for this review meeting is displayed as an aggregated roster that includes reviewers from multiple CSR Special Emphasis Panels of the Risk, Prevention and Health Behavior Integrated Review Group for the 2019/01 council round.
This roster for CSR is available at:

