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MTEC RESEARCH PROJECT NUMBER: MTEC-17-08-Multi-Topic-0104

EGS NUMBER: MT190002

TITLE: Validation of Wearable Sleep and Fitness Monitor with SleepTank Model

PRINCIPAL INVESTIGATOR: Steven Hursh, PhD

PERFORMING ORGANIZATION: Institutes for Behavior Resources, Inc.

CONTRACTING ORGANIZATION: Medical Technology Enterprise Consortium (MTEC)

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Fort Detrick, Maryland 21702-5012

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**Annual Technical Status Report for
Validation of Wearable Sleep and Fitness Monitor with SleepTank Model**

MTEC-17-08-Multi-Topic-0104

MT190002

Reporting Period: Effective Date – 01 January – 31 December '21

MTEC Research Project Awardee

Research Project Lead: Steven Hursh, PhD

Other Research Project Team Member: Lindsay P. Schwartz, PhD; Jaime K. Devine, PhD

Research Project Technical POC: Steven Hursh, PhD

Institutes for Behavior Resources, Inc.

2104 Maryland Avenue

Baltimore, MD 21218

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Submitted: January 24, 2022



2. Project Status

a. Accomplishments

- In 2021, IBR made great progress on our SleepTank mobile, watch, and web applications.
- The SleepTank mobile app has a stable and publicly available version on the Apple App Store. This app version has been used in two studies already, one examining sleep in nurses and one in air ambulance pilots.
- The SleepTank watch app, a stand-alone watch-based version of SleepTank is also fully functional and available through a private link for our study participants.
- The SleepTank clockface has been fully developed and provides a watch face-based version of SleepTank that doesn't require to user to navigate to a separate app. The clockface provides vibration notifications to the user of their SleepTank level. We believe this design will help make SleepTank more salient, increasing potential behavior change.
- Our CSV- data download has also undergone improvements to its stability and reliability. Future versions will not only download sleep and SleepTank data, but also app-usage data.
- We collected data from two operational trials of SleepTank, in nurses and air ambulance pilots. These data have been examined and some of the data have been submitted as a poster for the Military Health System Research Symposium 2021.
- Our trial with nurses is ongoing. Future data collection will incorporate the clockface app.
- We have also received approval for a third operational study in USAF servicemembers. This study is awaiting final updates to our clockface app before commencing recruitment.
- In late 2021, a new contractor was added to the team to support the SleepTank applications.

b. Reportable Outcomes

- Data collection and analysis from air ambulance pilots complete.
- Data collection with nurses using SleepTank has been paused in anticipation of the SleepTank clockface. Data collection should resume in the next quarter.
- Approval received for study with USAF members. Data collection with USAF members to begin recruitment in the next quarter
- Ongoing development and support of SleepTank web version.
- Upgrades and stabilization of the mobile app is ongoing

c. Progress Detail

In 2021, IBR has made great progress towards our goals. Our first goal was to develop our SleepTank algorithm into a multi-device application that can help user's track their sleep debt and improve their sleep hygiene. In the past year, we have worked on mobile, watch-based, clockface, and web versions of SleepTank. Our mobile version has been made available in the Apple App Store for use, and additional versions that include better design are forthcoming. Our watch-based app is fully functional, but is currently only available via private link for our study participants. Feedback from users encouraged us to create a version that provided them reminders of their SleepTank levels. To address this, we created the SleepTank clockface. This version of SleepTank is integrated into the clockface of Fitbit devices that have a display screen. The SleepTank circle and warning times are located next to the current date, time, steps, and heart rate displays. This prevents the user from having to navigate to a separate app to see their SleepTank information – they simply need to look at their watch. The clockface also provides the user with a notification of their warning times – their watch will vibrate and tell them which warning time they have reached when they reach that

time, as long as they are not already asleep. We have also developed a SleepTank web version, which will allow users to see a SleepTank dashboard that replicates the mobile app on a webpage. The web version design is complete and developers are currently working on connecting it to the SleepTank API. IBR has also developed a CSV-download function for study managers. If they are using SleepTank for an approved study, they can download an anonymized CSV with their participants' sleep and SleepTank data.

Our second goal was to test the usability and efficacy of SleepTank in operational environments. Two studies were run in 2021 to reach these goals. One study was with nurses and focused on the usability of the app. We received mixed feedback from them; primarily that they would forget to navigate to and use the mobile app. Data collection is ongoing, and a second cohort aims to incorporate the clockface app to make SleepTank information more available to them. Our other study was with air ambulance pilots. These data were analyzed and a poster presentation was submitted to the Military Health System Research Symposium.

Work in this past quarter has focused solely on app development. In October 2021, IBR transitioned development of the SleepTank apps to a new subcontractor. Because of this transition, development had been temporarily halted, but has resumed. With a new subcontractor, IBR will focus on the clockface development for our future studies. Currently, development of the app is moving at a faster rate.

There are two remaining studies from which data will be collected. One will be the second cohort of nurses and one with USAF service members. Both studies have all required approvals but are waiting for the final SleepTank clockface version to be available before resuming recruitment.

3. Future Plans

Our future plans are to finish the project in the next year. This coming quarter, we will aim to begin data collection for our final two research projects. We aim to complete data collection by June 1. We are currently waiting for final stable versions of the clockface before beginning recruitment. These studies will provide data on how SleepTank impacts sleep behavior in operational environments and are a critical test of SleepTank's efficacy.

4. Problems / Issues

a. Current Problems / Issues

Due to delays in development, we have had to delay data collection and analysis from our two remaining studies, which are intended to assess the usability and efficacy of SleepTank in operational environments. At this point in time, we are unable to run the entire study before our current deadline. We have reached out to MTEC about opportunities for extensions, but are awaiting final approval. While it is possible to complete our tasks with the limited data we already have, we believe that completing these studies in their entirety would provide the best picture of SleepTank's efficacy in operational environments.

b. Anticipated Problems / Issues

One anticipated issue is a delay of research/data collection due to unforeseen delays in app development. Our final study has an anticipated timeframe of 2 months. Delays in recruitment or data collection have extended us past the original December 1, 2021 deadline. If approved, our extension gives us a June deadline to complete the studies.

5. Financial Health

IBR requires no additional funds to complete this project. The project is in good financial health.

6. Personnel Effort



Personnel	Role	Percent Effort
Steven Hursh, PhD	Research Project Lead	98%
Jaime K. Devine, PhD	Research Project Team Member 1	97%
Lindsay P. Schwartz, PhD	Research Project Team Member 2	96%

7. Protocol and Activity Status

a. Human Use Regulatory Protocols

HRPO has determined our three current protocols to be exempt.

b. Use of Human Cadavers for RDT&E, Education or Training

None

c. Animal Use Regulatory Protocols

None

Annual Business Status Report for
Validation of Wearable Sleep and Fitness Monitor with SleepTank Model

MTEC-17-08-Multi-Topic-0104

MT190002

Reporting Period: Effective Date – 01 January – 31 December '21

MTEC Research Project Awardee

Research Project Lead: Steven Hursh, PhD

Other Research Project Team Member: Lindsay P. Schwartz, PhD; Jaime K. Devine, PhD

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Submitted: January 24, 2022

1. CURRENT STAFF

<i>Personnel</i>	<i>% of Effort on project</i>
Research Project Lead	98%
Research Project Team Member 1	97%
Research Project Team Member 2	96%

2. CURRENT EXPENDITURES

DIRECTIONS: FILL OUT TABLE A OR B DEPENDING ON CONTRACT TYPE. TABLE A IS FOR COST REIMBURSBLE CONTRACTS AND TABLE B IS FOR FIX PRICED CONTRACTS.

A. Cost Reimbursable Contracts: Complete only if your contract is Cost Reimbursable or Cost Plus Fixed Fee.

Expenditures should be reflective of cost incurred to date, not exceeding awarded project ceiling. Expenditures should coincide with the latest invoice for the reporting period. For cost reimbursable contracts please use the table below.

Contract Expenditures	Current QTR Expenditures	<i>Cumulative To Date Expenditures</i>
Labor (Personnel and Fringe)	\$	\$
Supplies/Materials	\$	\$
Travel	\$	\$
Equipment	\$	\$
Subcontractors and Consultants	\$	\$
Other Direct Costs	\$	\$
Indirect Costs	\$	\$
Total	\$	\$

B. Fixed Priced Contracts: Complete only if your contract is Fixed Priced.

Expenditures should be reflective of milestones that are **100% complete** and **invoiced** for. Milestones reported below should correspond to the Milestone Payment Schedule in the Project Award. **Milestones can only be invoiced for if they are 100% Complete.** Expenditures should coincide with the latest invoice for the reporting period. For fixed priced contracts please use the table below.

MTEC Milestone Number	Milestone Description	Due Date	Government Funds
1.	Procure wearable devices: First lot of 150 devices, with shipping	3/1/19	\$15,364
2.	Procure wearable devices: Second lot of 150 devices, with shipping	4/1/19	\$15,364
3.	Quarterly Report 1 (January – March, Technical and Business Reports)	4/25/19	\$ 0
4.	Purchase test off-the-shelf wearables devices	5/1/19	\$ 5,000
5.	SleepTank application design and specification for off-the-shelf wearables	7/1/19	\$ 29,518
6.	Quarterly Report 2 (April – June, Technical and Business Reports)	7/25/19	\$ 0
7.	Algorithm Validation Studies Complete	8/1/19	\$ 15,000
8.	Complete Development of SleepTank App	8/1/19	\$ 42,978
9.	Algorithm Validation Studies Data Analysis & Report	10/1/19	\$ 20,009
10.	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/19	\$ 0
11.	Annual Report 1	01/25/20	\$ 0
12.	Quarterly Report 4 (January-March, Technical and Business Reports)	4/25/2020	\$ 0
13.	Distribute and Support SleepTank™ application	6/1/2020	\$20,000
14.	Quarterly Report 5 (April-June, Technical and Business Reports)	7/25/2020	\$ 0
15.	Procure off-the-shelf wearable devices, with shipping	08/01/2020	\$18,251
16.	Quarterly Report 6 (July-September, Technical and Business Reports)	10/23/2020	\$ 0
17.	Validate usability/applicability of wrist-worn devices in the operational environment	12/01/2020	\$14,970
18.	Annual Report 2	01/25/2021	\$ 0
19.	Quarterly Report 7 (January-March, Technical and Business Reports)	04/25/2021	\$ 0
20.	Quarterly Report 8 (April-June, Technical and Business Reports)	07/25/2021	\$ 0
	Total Expenditures		\$196,454

C. Cost Share Contributions: Complete only if you're reporting Cost Share:

Cost sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work not directly paid for by the Government. There are two types of cost sharing: **(1) Cash:** Outlays of funds to perform the proposed project. Cash includes labor, materials, new equipment, and relevant subcontractor efforts. Sources include new IR&D funds, profit or fee from another contract, overhead or capital equipment expense pool. **(2) In-Kind:** Reasonable value of in-place equipment, materials or other property used in performance of the proposed project. All cash or in-kind cost sharing availability must be clearly and convincingly demonstrated by the Offeror. The Offeror will be required to provide financial reporting with appropriate visibility into expenditures of Government funds vs. private funds.

Funding Source (Cash)	This Period	Cumulative to Date
Cash	\$0.00	\$0.00
Labor Dollars	\$0.00	\$0.00
Indirect Labor Rates (Overhead/Fringe Benefits)	\$0.00	\$0.00
Travel	\$0.00	\$0.00
General & Administrative Services	\$0.00	\$0.00
Equipment (New)	\$0.00	\$0.00
Material	\$0.00	\$0.00
Other Direct Costs	\$0.00	\$0.00
Other *	\$0.00	\$0.00
Sub-Total	\$0.00	\$0.00
Funding Source (In-Kind)	This Period	Cumulative to Date
Use of Existing Equipment (Estimated fair market value)	\$0.00	\$0.00
Use of Existing Software (Estimated fair market value)	\$0.00	\$0.00
Intellectual Property (Estimated fair market Value)	\$0.00	\$0.00
Space (Land or buildings)	\$0.00	\$0.00
Sub-Total	\$0.00	\$0.00
Cost Share Total	\$0.00	\$0.00

3. STATUS OF MILESTONES – FILL OUT FOR ALL CONTRACT TYPES (all project milestones are to be included)

All project milestones from the Milestone Payment Schedule, in the project award, should be accounted for below.

MTEC Milestone Number	Milestone Description	Due Date	% Completed this Reporting Period	Cumulative % Complete
1	Procure wearable devices: First lot of 150 devices, with shipping	03/01/2019	100%	
2	Procure wearable devices: Second lot of 150 devices, with shipping	04/01/2019	100%	
3	Quarterly Report 1 (January - March, Technical and Business Reports)	04/25/2019	100%	
4	Purchase test off-the-shelf wearables devices	05/01/2019	100%	
5	SleepTank application design and specification for off-the-shelf wearables	07/01/2019	100%	
6	Quarterly Report 2 (April - June, Technical and Business Reports)	07/25/2019	100%	
7	Algorithm Validation Studies Complete	08/01/2019	100%	
8	Complete Development of SleepTank App	08/01/2019	100%	
9	Algorithm Validation Studies Data Analysis & Report	10/01/2019	100%	
10	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/2019	100%	
11	Annual Report 1	01/25/2020	100%	
12	Quarterly Report 4 (January-March, Technical and Business Reports)	04/25/2020	100%	
13	Distribute and Support SleepTank™ application	06/01/2020	100%	
14	Quarterly Report 5 (April-June, Technical and Business Reports)	07/25/2020	100%	
15	Procure off-the-shelf wearable devices, with shipping	08/01/2020	100%	
16	Quarterly Report 6 (July-September, Technical and Business Reports)	10/23/2020	100%	
17	Validate usability/applicability of wrist-worn devices in the operational environment	12/01/2020	100%	
18	Annual Report 2	01/25/2021	100%	
19	Quarterly Report 7 (January-March, Technical and Business Reports)	04/25/2021	100%	
20	Quarterly Report 8 (April-June, Technical and Business Reports)	07/25/2021	100%	

4. DEVIATION FROM PROJECT PLAN

There are currently no major deviations from the project plan aside from delays due to app development. No additional funds are requested.

Please name this annual report file as EGS#_Annual Report_Y# (For example MT160001.01_Annual Report_Y2)

Please submit as a PDF file.

Please make sure to fill in the page number on page 3 Table of Contents.

Don't forget to submit an updated Quad Chart as well. Please name the Quad chart file as EGS#_Quad Chart_Y#.