

TASK ORDER NUMBER: W81XWH-19-9-0001

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.

REPORT DATE: January 25, 2021

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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

Research Project No. MTEC-17-08-Multi-Topic-0104

EGS# MT190002

Reporting Period: Effective Date – 01 January 2020 – 31 December 2020

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.

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Baltimore, MD 21218

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Submitted: January 25, 2021



2. Project Status

a. Accomplishments

- Development of the SleepTank mobile app
- Progress on a web version of SleepTank
- IRB/HRPO exemption of two research studies in which SleepTank will be tested for usability and/or efficacy in operational environments

b. Reportable Outcomes

- Publication of the Zulu watch validation
 - Devine JK, Chinoy ED, Markwald RR, Schwartz LP, Hursh SR. Validation of Zulu Watch against Polysomnography and Actigraphy for On-Wrist Sleep-Wake Determination and Sleep-Depth Estimation. *Sensors (Basel)*. 2020 Dec 25;21(1):76. doi: 10.3390/s21010076. PMID: 33375557; PMCID: PMC7796293.
- The SleepTank iOS mobile app is now publically available on the Apple App Store
- The SleepTank Fitbit watch app is available to participating users via a download link
- CSV download website has been completed. This feature allows for download of Fitbit and SleepTank data for individuals in private study groups. It is currently available only to participating partners of IBR.
- HRPO has confirmed exemption of two ongoing studies: One to assess usability of SleepTank in Norwegian air ambulance pilots and one to test efficacy in nurses in the USA.

c. Progress Detail

The Institutes for Behavior Resources (IBR) has made good progress in the past year on the development and testing of SleepTank. The first public version of the SleepTank iOS mobile app has completed Beta testing and is now available on the Apple App store. The availability of the iOS app, Fitbit watch app, and CSV download feature has enabled us to move forward with testing the usability and efficacy of SleepTank.

We will be receiving secondary-use data from the University of Iowa School of Nursing. Nurses there will be wearing the Fitbit Versa 2 watch and using the SleepTank app for 6 weeks. IBR will received the deidentified data at the conclusion of the study. Additionally, IBR has HRPO approval (of exempt status) to conduct a study with SleepTank in Norwegian air ambulance pilots. There are currently 6 pilots screened and enrolled in the study. Data collection is planned to commence mid-January 2021.

3. Future Plans

In the coming quarter, IBR will collect SleepTank data from the Norwegian pilot study. IBR will also wait for University of Iowa to conduct its study and provide the deidentified data to IBR. IBR will also focus its development activity on the web version of SleepTank, which allows individual users to view their SleepTank data on a website. IBR will also continue to make improvements to the SleepTank apps as needed.

IBR has also identified another partner at RAF Alconbury, who is interested in collecting wearable data in a trial with US airmen. IBR is in the process of applying for HRPO approval for a secondary-use IRB to analyze this data.



4. Problems / Issues

On December 1st 2020, this project had a milestone to collect data on the usability of wrist-worn devices in operational environments. Due to delays because of the COVID-19 pandemic, our studies have been delayed. We are now collecting data in the above-described studies. Such data will allow us to address both the usability of wearables in operational environments as well as the specific usability and efficacy of the SleepTank feedback. Therefore, the studies addressing Milestones 20 and 21 will also address Milestone 17.

a. Current Problems / Issues

There are no current problems or issues with the project. Studies are underway and collecting data. The app development has delayed this project in the past, but an app-store ready version is now available. Due to these delays with the mobile app, the web version of SleepTank has been delayed as well. However, we anticipate the web version to be completed this coming quarter.

b. Anticipated Problems / Issues

Anticipated problems that could occur include a delay in receiving data from our study partners due to any problems with the completion of their studies. However, the IBR team is working closely with our partners to ensure they are able to complete their studies within their specified timeframe. Support is being provided to partners to help them use the SleepTank apps.

5. Financial Health

The study is financially on track. No additional funds are requested.

6. Personnel Effort

Personnel	Role	Percent Effort
Steven Hursh, PhD	Research Project Lead	75%
Jaime K. Devine, PhD	Research Project Team Member 1	72%
Lindsay P. Schwartz, PhD	Research Project Team Member 2	75%

7. Protocol and Activity Status

a. Human Use Regulatory Protocols

HRPO has determined both of our protocol submissions to be exempt. This protocol covered secondary-use data of SleepTank usage in nurses and data on SleepTank use in Norwegian air ambulance pilots.

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

Research Project No. MTEC-17-08-Multi-Topic-0104

EGS# MT190002

Reporting Period: Effective Date – 01 January 2020 – 31 December 2020

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 25, 2021

1. CURRENT STAFF

<i>Personnel</i>	<i>% of Effort on project</i>
Research Project Lead	75%
Research Project Team Member 1	72%
Research Project Team Member 2	75%

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.

<i>Contract Expenditures</i>	<i>Current QTR Expenditures</i>	<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
16.	Quarterly Report 6 (July-September, Technical and Business Reports)	10/23/2020	\$ 0
	Total Expenditures		\$163,233

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	3/1/2019	100%	
2	Procure wearable devices: Second lot of 150 devices, with shipping	4/1/2019	100%	
3	Quarterly Report 1 (January - March, Technical and Business Reports)	4/25/2019	100%	
4	Purchase test off-the-shelf wearables devices	5/1/2019	100%	
5	SleepTank application design and specification for off-the-shelf wearables	7/1/2019	100%	
6	Quarterly Report 2 (April - June, Technical and Business Reports)	7/25/2019	100%	
7	Algorithm Validation Studies Complete	8/1/19	100%	

8	Complete Development of SleepTank App	8/1/19	100%	
9	Algorithm Validation Studies Data Analysis & Report	10/1/19	100%	
10	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/19	100%	
11	Annual Report 1	01/25/20	100%	
12	Quarterly Report 4 (January-March, Technical and Business Reports)	4/25/2020	100%	
13	Distribute and Support SleepTank™ application	6/1/2020	100%	
14	Quarterly Report 5 (April-June, Technical and Business Reports)	7/25/2020	100%	
16	Quarterly Report 6 (July-September, Technical and Business Reports)	10/23/2020	100%	

4. DEVIATION FROM PROJECT PLAN

While there have been some delays in the project, there are no major deviations from the project plan. IBR is currently on track to complete the project in 2021.

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#.

Validation of Wearable Sleep and Fitness Monitor with the SleepTank™ Model

Insert Electronics Grants System (EGS) Number: MT190002

Award Number: MTEC-17-08-Multi-Topic-0104



PI: Dr. Steven Hursh

Org: Institutes for Behavior Resources

Award Amount: \$244,949

Study/Product Aim(s)

1. Validate the applicability of wrist-worn devices for improving sleep hygiene in the operational environment.
2. Demonstrate that an off-the-shelf device (e.g., Fitbit, Apple Watch, Zulu watch) with SleepTank™ increases the consistency of daily sleep in individuals working in an operational environment.
3. Demonstrate that feedback from SleepTank™ can improve sleep behavior in individuals.
4. Apply behavioral economics methods to facilitate commercialization of the proprietary software and determine appropriate market price for wearables enhanced by our technology.

Approach

1. IBR will use proprietary software to analyze sleep and provide, via SleepTank™, measures of awareness on sleep need.
2. IBR will validate the approach with both military and industry partners.

Fitbit Smartwatch App

iOS app



Accomplishment: 1) We have completed studies of the Zulu algorithm, the iOS app, and the watch app. 2) We have begun protocol review for studies testing the usability and efficacy of the apps

Timeline and Cost

Activities	CY	2019	2020/2021
Purchase and distribute Zulu		<div style="width: 100%; height: 10px; background-color: #92d050; position: relative;"><div style="width: 95%;"></div><div style="width: 5%; background-color: #4b0082;"></div></div>	
Develop and distribute off-the-shelf device apps		<div style="width: 100%; height: 10px; background-color: #92d050; position: relative;"><div style="width: 80%;"></div><div style="width: 20%; background-color: #4b0082;"></div></div>	
Zulu Algorithm validation study		<div style="width: 100%; height: 10px; background-color: #92d050; position: relative;"><div style="width: 95%;"></div><div style="width: 5%; background-color: #4b0082;"></div></div>	
Establish SleepTank efficacy and use in operational environment			<div style="width: 100%; height: 10px; background-color: #92d050; position: relative;"><div style="width: 100%;"></div></div>
Estimated Budget (\$K)		\$138,233	\$106,716

Project Goals/Milestones

CY19 Goal – Development of SleepTank app and initial Distribution to Partners.

- ✓ Purchase and distribute Zulu wearables
- ✓ Distribute Zulu mobile application
- ✓ Complete validation studies of Zulu sleep algorithm
- ✓ Develop watch and phone apps for off-the-shelf wearables

CY20/21 Goals – SleepTank Validation

- ✓ Distribute off-the-shelf wearables and Zulus for behavioral validation studies
- Demonstrate use of watches in operational environments
- Demonstrate efficacy of SleepTank in improving sleep behavior

Comments/Challenges/Issues/Concerns

- HRPO has exempted our protocols for two studies. These studies have starts dates in January and February 2021. They will assess usability and efficacy of SleepTank in operational settings.

Budget Expenditure to Date

Invoiced Amount to Date: \$163,233

Updated: 1/19/2021