Annual Business Status Report for

Validation of Wearable Sleep and Fitness Monitor with SleepTank Model

MTEC-17-08-Multi-Topic-0104

Reporting Period: 26 February – 31 December 2019

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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Submitted: January 25, 2020

MTEC
Medical Technology Enterprise Consortium

1. CURRENT STAFF

Personnel	*% of Effort on project*
Senior Scientist	42%
Lead Scientist	37%
Staff Scientist	46%

2. CURRENT EXPENDITURES

DIRECTIONS: FILL OUT TABLE A OR B DEPENDING ON CONTRACT TYPE. TABLE A IS FOR COST REIMBURSBALE 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**	***Cumulative To Date Expenditures***
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
9.	Algorithm Validation Studies Data Analysis & Report	10/1/19	$ 20,009
11.	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/19	$ 0
	Total Expenditures		$ 100,255

C. Cost Share Contributions: <u>Complete only if you're reporting Cost Share:</u>

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%	
9	Algorithm Validation Studies Data Analysis & Report	10/1/19	100%	
11	Quarterly Report 3 (July – September, Technical and Business Reports)	10/25/19	100%	

4. DEVIATION FROM PROJECT PLAN

Any major deviations from the agreed to project plan shall be explained with a discussion of proposed actions to address the deviations.

A current problem with adhering to our timeline was a delay in receiving data from one of our military partners. We received the data in October and the report milestone (#9) was completed on 12/20/2020. While our algorithm validation study and report was delayed, it did not significantly impact the project as a whole. The algorithm validation studies are specific to the Zulu watch and therefore do not impact our ability to move forward with the ultimate goal of creating a SleepTank app for commercially available watches.

Additionally, the full development of the SleepTank app has been delayed due to restricting of the data processing. Initially, the mobile app collected sleep data from the Fitbit server and processed it through the SleepTank algorithm on the phone. However, with the addition of the web interface for SleepTank, it was determined that a more efficient way to process the data is to do so on a cloud-based server, and then send that information to the phone app. Therefore, the mobile app data processing must be reconfigured to a server, which has caused delays in the deliverable.

Annual Technical Status Report for

Validation of Wearable Sleep and Fitness Monitor with the Sleep Tank Model

Research Project No. **2019-330-001**

Reporting Period: Effective Date – February 26 – December 31 2019

MTEC Research Project Awardee

Institutes for Behavior Resources

Research Project Technical POC

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Submitted: January 25, 2020

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1. Project Status

a. Accomplishments

1) IBR has completed the validation of the Zulu sleep algorithm against PSG

2) IBR has identified two (2) off-the-shelf wearables for SleepTank

2) IBR has completed the development of the SleepTank Watch App for the Fitbit watch

3) IBR has started research projects on the usability and efficacy of the Zulu watch with SleepTank

4) IBR has made significant progress on a mobile app for SleepTank

b. Reportable Outcomes

1) The Fitbit watch app

2) Data on the efficacy on SleepTank in an internal study

3) Final report for the Zulu algorithm validation study

c. Progress Detail

1) Zulu Validation Study:

IBR has completed a study on the Zulu sleep algorithm against PSG with our partners at the Naval Health Research Center. Our report on that study was submitted in December 2019. Briefly, we found that the Zulu watch is sufficiently accurate in determining the total sleep time, sleep onset, time of awakening and deep sleep in comparison to polysomnography, the gold standard of sleep measurement. In addition, the Zulu watch is accurate in sleep-wake determination when compared to a validated actigraph, the AMI Motionlogger.

2) Zulu usability data:

IBR has received some data from our partners at UPS, who conducted a brief survey on the Zulu watch. They indicated that 92% of participants (n=13) found the watch usually or always accurate. Additionally, 62% of participants found that the SleepTank information was informative. These data are being further analyzed and will be part of a complete report on the usability of the Zulu watch in the future. IBR has also received data from The University of South Australia, which used the Zulu watches in a group of students to measure its usability. Those data are currently under analysis and will also be incorporated into a report on the usability of the Zulu watch.

3) Off-The-Shelf Wearables Identified:

The Fitbit and Apple Watch have been identified as suitable devices for the SleepTank app. Both have large populations of users, increasing any potential users for SleepTank. The Fitbit devices score sleep with acceptable accuracy and provide a platform for using that sleep in the SleepTank algorithm. The

watches have battery life from 3 days to one week, as well as durable and stylish designs that are appealing to the general user.

The Apple Watch does not currently score sleep, but we are able to both score sleep using validated sleep-scoring algorithms, and process that scored sleep through the SleepTank model for display on the watch. The battery life is limited to 24-hours, but the watch provides good computing power and data storage.

4) Fitbit Watch App:

An app for the Fitbit watch is complete and displays the user's SleepTank levels, as well as low-level warning times:

5) SleepTank Mobile App:

Our SleepTank mobile app is in the final stages of completion. Delays are related to a restructuring of the data processing done in the app versus a server. This restructuring is detailed in Problems/Issues. We still expect the app to be completed in the first quarter of 2020.

6) Web Interface:

An additional feature of the SleepTank app will be the availability of a web interface to view and download data. The data viewed on the web will be the same or similar to those viewed on the mobile app. However, the interface will have the additional feature of a CSV download for an individual's sleep and SleepTank data. The CSV download feature will also allow researchers to download the data from any study participants, with explicit permission from the participants themselves.

2. Future Plans

In the next quarter we will continue to test the Fitbit SleepTank app as well as develop a version for the Apple Watch. We will also be distributing this app to interested commercial and military partners. We

intend to receive feedback on the usability of the apps as well as use them in studies to assess the efficacy of the SleepTank app on sleep behavior.

3. Problems / Issues

a. Current Problems / Issues

A current problem with adhering to our timeline was a delay in receiving data from one of our military partners. We received the data in October and the report milestone (#9) was completed on 12/20/2020. While our algorithm validation study and report was delayed, it did not significantly impact the project as a whole. The algorithm validation studies are specific to the Zulu watch and, therefore, do not impact our ability to move forward with the ultimate goal of creating a SleepTank app for commercially available watches.

Additionally, the full development of the SleepTank app has been delayed due to restructuring of the data processing. Initially, the mobile app collected sleep data from the Fitbit server and processed it through the SleepTank algorithm on the phone. However, with the addition of the web interface for SleepTank, it was determined that a more efficient way to process the data is to do so on a cloud-based server, and then send that information to the phone app. Therefore, the mobile app data processing must be reconfigured to a server, which has caused delays in the deliverable.

b. Anticipated Problems / Issues

While there are no technical problems with our project, the development of the app is taking longer than anticipated. We are currently planning on adding developers to our team to expedite this process.

4. Financial Health

Our project is currently on track financially in regards to total expenditure. However, IBR has been delayed in submitting invoices to MTEC because of delays in the completion of Milestone 8. This Milestone is expected to be completed this quarter.

5. Personnel Effort

Provide names of current staff along with their roles and percent effort of each on this project. Add additional rows if necessary to list the complete team. If there is more than one project on this award, breakdown according to each project (one table per project).

Personnel	Role	Percent Effort
Dr. Steven Hursh	Senior Scientist	42%
Dr. Jaime Devine	Lead Scientist	37%
Dr. Lindsay Schwartz	Staff Scientist	46%

6. Protocol and Activity Status

IBR has submitted protocol to HRPO for approval. The attached protocol approval has already been approved by Salus IRB. We are currently waiting on approval from HRPO.