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TITLE: Sensorimotor Assessment and Rehabilitative Apparatus

PRINCIPAL INVESTIGATOR: Michael Schubert

CONTRACTING ORGANIZATION: Johns Hopkins University Baltimore, MD 21218

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In veterans and civil	ians exposed to blast	or blunt head trauma	or those suffering fron	n inner ear dis	sorders, a clinical pattern of damage to the	
auditory, visual, and	l vestibular (inner ear	balance mechanism)	sensorimotor systems	has emerged;	collectively known as multi-sensory	
impairment (MSI).	MSI related symptom	s affect $\sim 300-500/100$	0000 population. The j	purpose of the	s study is to examine subjects for	
sensorimotor impair	ments within the visu	al and vestibular syste	ems using a portable te	chnology tha	t rapidly and unobtrusively measures how	
these interdependen	t systems are function	ally integrated. We ca	all this device SARA,	Sensorimotor	Assessment and Rehabilitation Apparatus.	
The scope of the property $1 = 10^{-12}$	bject involves recruiting	ng n=42 Veterans from	n the War Related IIIn	ess and injury	Study Center (WRIISC) in East Orange	
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base a significant ocular misalignment in their ave position relative to healthy controls. This finding suggests that SADA may serve as an						
excellent proxy of more elaborate laboratory equipment that requires expertise in use is cumbersome and impractical for many unique						
environments		ory equipment that rea	Jun es expertise in use,		ne and impractical for many anique	
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1. INTRODUCTION

Exposure to brain injury via blast or blunt mechanisms disrupts multiple sensorimotor systems simultaneously in nearly 20% of veterans of the Gulf War and OIF/OEF campaigns, causing physical, sensory, cognitive, and behavioral/emotional changes. Therefore, a significant population of our wounded veterans suffer long-term functional consequences including visual deficits, postural and locomotor instabilities, disorientation, dizziness, sensitivity to visual and body motion, and an impaired ability to read. A clinical pattern of damage to the auditory, visual, and vestibular (inner ear balance mechanism) sensorimotor systems has emerged, which has collectively been given the name multi-sensory impairment (MSI). In the US civilian population, MSI related symptoms are also a common sequelae of damage to the inner ear and mTBI, collectively affecting ~ 300-500/100,000 population. Therefore, irrespective of the environment (military or civilian) or cause (mTBI or peripheral vestibular injury), the inner ear is commonly involved when symptoms of MSI are experienced. The purpose of this study is to examine subjects for sensorimotor impairments within the visual and vestibular systems using a portable technology that rapidly and unobtrusively measures how these interdependent systems are functionally integrated.

We call this device SARA, Sensorimotor Assessment and Rehabilitation Apparatus. The scope is to validate SARA as a battery of the unique functions of the vestibular and oculomotor systems (in particular, eye alignment, visual acuity during head motion, and gait). Ideally, we hope to use SARA to build an Index score that strongly suggests injury to the vestibular and oculomotor systems. The scope of the project involves recruiting n=42 Veterans from the War Related Illness and Injury Study Center (WRIISC) in East Orange NJ and n=42 civilian subjects with vestibular hypofunction from the Johns Hopkins University School of Medicine Clinics (otolaryngology, rehabilitation, and neurology). We will collect age-matched healthy control subjects at the Johns Hopkins site. The duration of the study was three years, we have entered a No-Cost Extension.

2. KEYWORDS

Multisensory Impairment, Vestibular, Visual, Dynamic Visual Acuity, Imbalance, Mild Traumatic Brain Injury, Sensorimotor, Assessment, Portable, Sensors, Otolith, Semicircular Canal, Gait

3. ACCOMPLISHMENTS

a. Major Goals

The major goals of this project as established by the approved SOW include

I. Establish project management system to ensure success of project

This goal is 100% complete, though did take 11 months to complete. The 11-month duration delayed data collection.

We continue to have biweekly meetings at JHU, monthly meetings with the WRIISC (phone) and 'as-needed' conversation/email with both JHU and WRIISC grants management offices to ensure adequate oversight from expenditure of funds, human subjects protection, salary support, data collection and progress towards the major goals. In addition,

- 1. Roughly once a quarter, a member of the JHU research team travels to WRIISC to assist with data collection and to ensure an 'in person' visit to troubleshoot any difficulties that have arisen.
- 2. The PI has a monthly meeting with the JHU grant management office to go over expenditures of this award and the PI received monthly summary statements of the budget.

Per this 1st major goal, the following milestones have been achieved:

- a. Both sites have trained individual's independently collecting data. Both sites are actively collecting data.
- b. Both sites have the necessary software and hardware to data collect.
- c. Only the JHU site has a trained Physical Therapist to carry out the rehabilitation AIM 3. Please see Section 5. (Changes/Problems) regarding the Physical Therapist hire at the WRIISC.

II. Obtain Institutional Review Board approval at VA NJ and JHU

This goal is 100% complete.

Per this 2nd major goal, the following milestones has been achieved

- a. HRPO/ACURO Approval
- b. Local IRB Approval

III. Develop recruitment plan to identify and enroll Veterans with MSI.

This goal 100% complete.

Per this 3rd major goal, the following milestone has been achieved

a. Local IRB approval at both sites of the recruitment flyers and telephone scripts needed to assist with subject recruitment.

IV. Determine the effectiveness of SARA to identify vestibular function

We projected this Major Goal to be complete within the 3-year total grant duration. However, the delayed start due to acquiring human use protection approval from HRPO put us behind. We have made good progress. At JHU, we have collected data on 33 patients. This is 79% completed. We are finished collecting data in the healthy controls, which we modified (with Science Officer approval) to reflect controls grouped by age. The original sample size for healthy controls that we projected to collect was to be 42, however, with age-matching we have

been able to complete healthy control data collection (n=27). The mean age of patients is 54 ± 11 years compared with healthy controls being 51 ± 14 years.

At the East Orange VA Hospital (WRIISC) we have collected data on n=39 veterans. This is 93% complete. In April of 2017, with approval from Dr Wang, our science officer, we had revised our recruitment projections as contingency in case our recruitment did not increase pace. We were largely successful in catching up to our projected recruitment numbers. Please see updated projections (**green shading, Table 1**).

	Projected Year 1		Actual	Year 2			Actua to	l Year (Date	3	Total to Date	NCE
Target Enrollment (per quarter)	Projected	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		2019
JHU VH	16	2	5	5	2	3	3	13	3	33/42	9
JHU HC	5	0	0	10	15	2	*	*		27*	Na
Total Screened	40	4	10	15	16	5	13	20		83	
East Orange VA Hospital (WRIISC)	2	2	2	9	9	6	9	2	1	39/42	2
Total Screened	4	0	0	15	15	41	20	0	91	119	
Target Enrollment (recruited only)	23	4	7	24	26	11	12	15		107	

Table 1	. Revised	recruitment
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Green shading – projected recruitment; * data collection complete; na – not applicable; Red text denote subjects recruited to date.

Based on this revised projection, we expect the total subject recruitment per site will be n=42 patients from JHU, n=27 controls from JHU and the VA, and n=42 at VA site. For the patient subjects, <u>these are the original projected numbers</u>. As above, based on age-matching, we have been able to reduce our projected numbers from n=42 to n=27 for the healthy control subjects.

We have requested and been granted a No-Cost Extension (NCE), based in part on discussions (email) with Dr Wang - who suggested considering a NCE. This was requested to complete data collection and to examine possible rehabilitation efforts at the VA hospital.

What has been accomplished under these goals? We have three Aims for this study:

AIM I. Correlate our behavioral measure of binocular alignment symmetry (via SARA) against gold standard measures of otolith function and visual function in an mTBI, vestibular deficit, and age-matched control population.

- AIM II. Investigate difference in dynamic visual acuity for near versus far viewing as a means to distinguish vestibular oculomotor from visual oculomotor control dysfunction in an mTBI, vestibular deficit, and an age-matched control population.
- AIM III. Investigate how well our MSI test (SARA) can predict those veterans and civilians with vestibular hypofunction that respond well to vestibular rehabilitation intervention.

The major activities involved in the reporting period representing this 3rd year have been extensive. We now have published four research manuscripts directly related to the aims of this award:

- Beaton K, Shelhamer MJ, Roberts DA, Schubert MC. A Rapid Quantification of Binocular Misalignment without Recording Eye Movements: Vertical and Torsional Alignment Nulling. *J Neurosci Methods*. 2017 May 1;283:7-14. PMID: 28300605.
- 2. Beaton K, Schubert MC, Shelhamer MJ. Assessment of vestibulo-ocular function without measuring eye movements. *J Neurosci Methods*. 2017 May 1;283:1-6. PMID: 28336357.
- 3. Schubert MC, Stitz J, Cohen HS, Sangi-Haghpeykar H, Mulavara, AP, Peters BT, Bloomberg JJ. Prototype tests of vertical and torsional alignment nulling for screening vestibular function. *J Vestibular Research*. 2017
- 4. Kim KJ, Gimmon Y, Sorathia S, Beaton KH, Schubert MC. Exposure to an extreme environment comes at a sensorimotor cost. *Nature Microgravity*. 2018

A fifth manuscript has been accepted and is in revision:

5. Using inertial sensors to quantify balance and gait performance during the tandem walking test. *Sensors.* 2018

A 6th manuscript has been submitted and is in peer review:

i. Veterans Have Greater Variability in Their Perception of Binocular Alignment. *PLOSOne*

In the past year, we presented SARA related research at the Combined Sections Meeting of the American Physical Therapy Association. *Vertical and Torsional Alignment Nulling: A Rapid Quantification of Binocular Misalignment without Recording Eye Movements*.

Aim I

We have developed the Vertical Alignment Nulling and Torsional Alignment Nulling tasks (VAN, TAN) to examine for any misalignment in oculomotor position. The task asks subjects to adjust a movable blue line so that it lines up horizontally with a stationary red line and both thus appear as a single line. If the right eye is elevated above the left eye (**Figure 1C**) or if the right eye is rotated (i.e. clockwise) away from the left eye (**Figure 1D**), the subject will mis-align the two lines. We test in both upright and supine position to examine differences in oculomotor position due to musculoskeletal or vestibular (otolith) injury. For example, when subjects lie supine, the vestibular contribution to an abnormal skew (vertical eye displacement as in **Figure 1C**) is abolished and the skew resolves (as in **Figure 1B**), yet a musculoskeletal or cranial nerve injury to that same eye muscle would not change and the skew would still be present.



Figure 1. Examples of ocular misalignments inferred by VAN and TAN results. (A) The subject repositions the moving line (blue in this example) until it appears in line with the stationary line (red), thereby positioning each line on the center of each retina. Binocular misalignment is inferred from the relative positioning of the lines at the end of each trial. (B) If the subject has perfect binocular alignment, then the lines will be perfectly aligned at the end of the trial. (C) If the subject sets the right line above the left line during VAN, we infer that the right eye is elevated above the left eye. (D) If the subject orients the right line clockwise relative to the left line in TAN, we infer that the right eye is extorted relative to the left eye.

To date, the most exciting result of our portable measure of ocular alignment is that it can distinguish veterans from healthy controls. This result has been submitted for publication. Interestingly, the difference between the two groups is their variability, not their mean scores. The veterans greater variability in scoring VAN or TAN in either upright or supine positions!



Figure 2. Box and whisker plot establishing greater variability of VAN and TAN scores during both upright sitting and supine test positions in the Veterans subjects (VETS) compared with control subjects (CTL) (p<0.05).

We believe this result will enable us to determine a SARA Index Score – a score that will consider VAN TAN, but also the other measures (Dynamic Visual Acuity, DVA – Aim II) and kinematic gait data (component of Aim III).

In the veterans, we have measured otolith function using cervical and ocular vemp. This was a part of our design in order to establish if the veterans had otolith dysfunction. Our data found that one third of veterans had an absent cVEMP response (saccular dysfunction, either right or left), the other 2/3 had either a normal or inconclusive result. For oVEMP testing, more than half (~55%) had an absent response (dysfunction, either right or left) with the other 45% being either normal or inconclusive. Reasons for VEMP testing to be inconclusive include motion artifact or indeterminable waveforms. This means that 85% of the veterans with abnormal VAN and TAN Scores in fact did have abnormal otolith function.

We have also collected measures related to subjective experience and physical performance (**Table 3**). Interesting, neither presence of a mild traumatic brain injury (PCL score) nor depression (P:HQ8 score) contributed to the veterans abnormal variability in scoring VAN and TAN. Instead, it appears the abnormal otolith **function** utricular is the cause. This is encouraging and suggests VAN and TAN can detect pathology in chronic patients (veterans) with dizziness.

	Physical B	ehavior Measur	es		
DGI	TUG (sec)	10M (m/s)	^2 min wall	k (m)	
22.1 ± 2.2	9.7 ± 2.3	1.5 ±0.4	145.7 ± 21		
Categorization Measures			5		
*PCL	VADL	VSS	PHQ8	ABC	^a DHI
40.4 ±15.6	2.1 ± 1.6	10.7 ± 10.4	7.6 ± 5.6	83.5 ± 13.9	30.3 ± 28.1

Table 3.	Physical	Behavior a	and Sub	iective N	leasures.
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Italics denote abnormal score; PCL – measure of PTSD; VADL – Vestibular Disorders Activities of Daily Living; VSS – vertigo symptom scale; PHQ8 – measure of depression; ABC – activities-specific balance confidence scale; TUG – timed up and go; DGI – dynamic gait index; DHI – dizziness handicap inventory; M – meter; * scores > 37 are positive for suffering PTSD; ^a scores > 16 significant for perceiving a handicap from dizziness; ^ abnormal compared with age matched controls

Aim II

We developed a second measure of oculomotor function on the handheld tablet using Dynamic Visual Acuity (DVA). DVA tasks subjects to identify a letter that flashes on a monitor only when the head is moving above 120 deg/sec. We are examining DVA while looking at near (.5m) and far (2m) distances while the subject makes active up, down, left and right head rotation. We hypothesized that near target viewing distances would be more difficult than far target given the combined linear and angular vestibulo-ocular reflex effort to stabilize the eyes. Our data reveal that all 3 groups (civilian with surgical deafferentation; veterans with dizziness; and healthy controls) have worse DVA during near target viewing (**Figure 4**). Roughly, the DVA scores in the patient subjects for 'Near distance' are 2-2.5 times worse than for 'Far distance' and nearly 9 times worse than healthy controls.





Figure 4. Mean and 1 SD Dynamic Visual Acuity (DVA) score for near (50cm) and far (500 cm) target distance across Control (top), Veterans with dizziness (middle) and civilians with 8th cranial nerve section (Bottom, UVD). Each group has worse DVA scores during Near target viewing distance (handheld 50cm) compared with far target distance (500 cm).

Far Near

However, when we compare the subjects with surgical nerve section, they have worse DVA scores than either the Veterans or Control subjects (**Figure 5**).



Figure 5. Mean and 1 SD plot comparing i an assume DVA in patients subjects with eighth cranial nerve section (UVD), Veterans with dizziness (VETS), and healthy control subjects. LogMAR – logarithm of the minimum angle resolvable. A score of 0 Logmar denotes 20/20 acuity, while a score of 1 indicates 20/200 legal blindness.

When we compare ipsi-rotation and contra-rotation yaw head rotations, we don't see much difference in DVA scores (**Figure 6**).



Figure 6. The civilian subjects with surgical nerve deafferentation surgery have no real difference for DVA between ipsi and contralesional yaw head rotation.

b. Gait (component of Aim III)

While not a direct aim or goal of our project, but a sub-component of Aim III, we have quantified gait using five wireless sensors (Aim III measures fall risk and collects outcomes related to gait) attached to each ankle, the trunk, the pelvis, and the head. To process data using these sensors, we have developed new measures of balance and posture performance. As an example, **Figure 7** illustrates the sway area of a subject standing on foam before and after performing a rehabilitation task.



Figure 7. Sway Area measured by portable, wireless sensors during standing on Foam. A. Body schema with the location of the inertial measurement units (IMU) (red circles), B. Postural sway during quite standing as measured from the IMUs placed as the head, trunk, pelvis, right and left ankles. Red traces represent the sway path. The dashed blue line represents sway area. Notice the decrease of sway over time since starting the training.

We are also measuring gait kinematics, and creating new variables to measure variability, **Figure 8**.



Figure 8. Examples of ML displacements during Tandem walking in health control and a patient with unilateral vestibular deafferentation. A. Healthy control Eyes Open (top) and Eyes Closed (bottom) with sensor data from head, upper trunk, and pelvis. B. Patient with UVD (top: EO, bottom: EC).

c. Rehabilitation (component of Aim III)

We are collecting functional outcome variables that include the Dynamic Gait Index, the Timed Up and Go test (TUG), gait speed (m/s), and the 2-minute walk test, (**Table 2**). In both patient cohorts (UVD and Veteran), the DGI (scores > 20 out of 24 possible) and the TUG scores (<13sec) are normal – suggesting they are not sensitive indicators to identify fall risk at the time of measurement (Bischoff et al 2003). The mean gait speed of our patient subjects is borderline slow depending on gender. The two-minute walk test appears to be normal in our patient subjects, based on healthy age-matched subjects 177-191 meters depending on gender (Bohannon et al 2015).

Table 2. Fu	inclibilat Galt Measures			
	DGI (Total Score 0-24)	TUG (<13sec)	Gait Velocity (m/sec)	Two Minute Walk Test (meters)
UVD	20.6 ± 3.8	8.6 ± 1.99	1.2 ± 0.26	160.1 ± 23.4
Veterans	21.6± 2.9	9.7 ± 2.18	1.4 ± 0.32	151 ± 20.6

Table 2. Functional Gait Measures

Oddly, however is the significant perception of disability that our subjects are reporting. Our civilian patient (UVD) subjects have Activity-specific Balance Confidence score (ABC) scores (69 \pm 17) that are abnormal but not considered a risk for fall given the score is > 67%.

The Dizziness Handicap Inventory is measure of perceived disability spread across three subcomponents (physical, functional, emotional). Values between 16-34 points suggests patients perceive a mild disability (**Table 3**). Both Veteran and civilians subjects with surgery to remove the 8th cranial nerve report significant DHI scores, but the surgical group cohort is worse (Table 3).

Table 3.	Perception	of Disability	as Measured	bv	ABC and DHI
I GOIC CI	rereeption			~ .	

	ABC_PERCENT	DHI Physical (0-28)	DHI Emotional (0-36)	DHI – Functional (0-36)	DHI Total (0-100)
UVD	69 ± 17	13.9 ± 7.3	10.3 ± 8.4	17.3 ± 9.0	41.3 ± 20.7
Veterans	84 ±14.8	8.7 ± 9.6	7.1 ± 7.3	8.1 ± 7.4	24.9 ± 23

Opportunities for training and professional development?

There was never an intention/purpose to train or provide professional development. However, in the past, discussions with clinicians from the WRIISC suggested interest in the PI delivering a continuing education. This has not developed any further. The PI remains interested to do so, if feasible and the VA warrants it valuable.

Dissemination of Results to communities of interest

In the last year, we published one research manuscript and have one In Press and a 3^{rd} in Review. We have presented one abstract to relevant communities of interest –

d. Combined Sections Meeting of the American Physical Therapy Association.

Plans for next reporting period

We will complete data collection in this NCE and attempt to collect some data on the effects of rehabilitation in veteran subjects. Finally, we intend to develop an index score of SARA that will consider the three primary sensorimotor functions (ocular alignment, visual acuity during head rotation, gait kinematics). We will continue to analyze the data and publish meaningful results.

4. IMPACT

The principal disciplines of this research project are to develop robust measures of sensorimotor function that can be delivered in environments that do not allow the space for cumbersome laboratory equipment, that do not require specialized training for use, and do not involve any

invasive procedure to gather relevant function of multiple medical systems.

During this 3rd year, of our efforts have revolved around patient recruitment and data analysis.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology? Nothing to report

Nothing to report.

5. CHANGES/PROBLEMS

Unanticipated Problem

We continue to have difficulty identifying a physical therapist at the WRIISC site to carry out the rehabilitative component of the study (see below). In the early summer of 2018, we identified a physical therapist (PT) from Kessler Institute that expressed interest delivering vestibular rehabilitation for the veteran subjects. He began the accreditation process but towards the end of Summer expressed dissatisfaction with the time it was taking. Unfortunately, in September he informed me of his withdrawal of his application, citing he did not have enough time.

We will continue attempts to identify a PT to treat the veterans; however we remain skeptical. Additionally, our funding is spent down and we may have some difficulty finding compensation for this individual.

Changes to expenditure

We have not had any significant change in expenditure.

Changes to human subjects

There has been no change to care of human subjects.

6. PRODUCTS

The VAN and TAN technology has been awarded a patent (mentioned in Year 1).

The following papers have been published:

- 1. Beaton KH, Schubert M, Shelhamer M. Assessment of vestibulo-ocular function without measuring eye movements. J Neurosci Methods. 2017 PMID: 28336357
- Beaton KH, Shelhamer MJ, Roberts DC, Schubert MC. A rapid quantification of binocular misalignment without recording eye movements: Vertical and torsional alignment nulling. J Neurosci Methods. 2017 May 1;283:7-14. doi: 10.1016 PMID: 28300605
- 3. Schubert MC, Stitz J, Cohen HS, Sangi-Haghpeykar H, Mulavara, AP, Peters BT, Bloomberg JJ. Prototype tests of vertical and torsional alignment nulling for screening vestibular function. J Vestibular Research. 2017;27(2-3):173-176. PMID: 29064832
- 4. Kim KJ, Gimmon Y, Sorathia S, Beaton KH, Schubert MC. Exposure to an extreme environment comes at a sensorimotor cost. *Nature Microgravity*. 2018

A fifth manuscript has been accepted and is in revision:

5. Using inertial sensors to quantify balance and gait performance during the tandem walking test. *Sensors.* 2018

Four abstracts have been presented in poster or oral presentation:

- 1. Military Health Science Research Symposium (August 2017)
- 2. APTA combined sections meeting (February 2017, 2018)
- 3. Association for Research in Otolaryngology (February 2017)
- 4. Middle East Neurotology Seminar (April 2018)

One additional abstract has been accepted for poster presentation:

1. APTA combined sections meeting (January 2019). *Gaze stability post unilateral vestibular de-afferentation surgery is still impaired after 5 weeks of vestibular rehabilitation*.

We have no books, websites, or to submit.

7. PARTICIPANTS AND OTHER COLLABORATING ORGANIZATIONS

Ten individuals across two institutions (Johns Hopkins and the East Orange VA (WRIISC)) have worked on the project. There has not been any change in either the PI or any of the senior personnel in this reporting period. The following effort per personnel over the last year upto the NCE are

For the past year, the Effort of personnel are listed in **Table 2**. For the NCE year, the finalized percentage of efforts are still being determined, but roughly are listed in **Table 3**.

		Effort
a. Johns Hopkins	CALENDAR	on
	MONTHS	PROJ.
Dr Michael Schubert	6	50%
Mark Shelhamer	0.68	8%
Dr. Rodhe	1.2	10%
Daniel Gold	1.2	10%
Dales Roberts	3	25%
Jennifer Millar	4.8	40%
(Yoav Gimmon 1/4/16 -9/2018)	12	100%
b. East Orange VA		
Jorge Serrador	0.6	5.07%
Research Assistant	0	0%
Research Assistant, Migdalm, Kamila	10	80.0%
Research Engineer, Ghobreal, Bemin	0.6	5.0%
c. U Miami		
Gailey, Robert	0.12	1%

Table 2. Effort and Personnel of final Year 3

	Kim, Kyoung Jae	0.84	7%
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Table 3. Moving forward, the effort and personnel during the NCE will be:

a. Johns Hopkins	CALENDAR	Effort on
	MONTHS	PROJ.
Dr Michael Schubert	1.8	15%
Daniel Gold	1.2	10%
Jennifer Millar	0.6	5%
b. East Orange VA		
Jorge Serrador (Site PI)	TBD	TBD
Bemin Ghobreal (Engineer)	TBD	TBD
Physical Therapist (TBD)	TBD	TBD
Kelly Brewer (Research Assistant)	TBD	TBD
c. U Miami		
Gailey, Robert (Site PI)	0	0%
Kim, Kyoung Jae (Signal Processing		
Engineer)	0.84	7%

TBD – to be determined

Change in Active Other Support Nothing to Report.

What other organizations were involved as partners?

Organization Name: Veterans BioMedical Research Institute

Location of Organization: 385 Tremont Ave., Bldg 11, Room 117 B, East Orange, NJ Partner's Contribution to the project: Grant provides financial support to the subsite; Facilities, Collaboration

References

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8. SPECIAL REPORTING REQUIREMENTS None to report

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