TRANSLATIONAL SCIENCE AT THE NEURAL INJURY CENTER

MUS Research and Economic Initiative

2nd Quarterly Report

November 2015-January 2016

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Objective 1: Expand current clinical capabilities of the Neural Injury Center (NIC) and support translational research.

a) Hirings:

- The Administrative Assistant has been hired and is now being trained on all NIC-related tasks. She is working on all applications for Medicare and VA Choice status.
- The Clinical Research Coordinator has been hired and has been working on identifying clinical research grant and contract opportunities
- The Neuropsychologist position has been advertised for several months, and we are currently exploring various ways to address the need for an on-site neuropsychologist (including part-time contracts or consulting agreements with local clinicians). Active discussions are underway with two potential neuropsychologists.

b) Equipment:

• N/A

c) Progress towards milestones:

- A student veterans' resource website was fully finalized and the Neural Injury Center website was finalized to help with sharing our resources and with patient recruitment. The student veterans' resource site is also linked to the Vets Office on campus and to the main UM website.
- A new brochure that includes our new website address and other targeted modifications was created to assist with informing student veterans of our services. It will be printed the first week of February and widely distributed thereafter.
- A short video is being produced over the next three weeks to highlight the NIC's services, technologies and research.
- A very successful TBI continuing medical education conference was held in November of 2015.
 Evaluations were summarized and shared. 140 clinicians from across the state attended, and feedback was uniformly excellent. Through this conference, new external scientific collaborations were also established with NIC investigators.
- Follow-up has been completed by the Chief Operating Officer on all previously screened student veterans to track status and offer additional assistance as relevant and needed.
- The Chief Operating Officer presented information on the NIC to a group of incoming student veterans at the Spring Semester Vets Orientation.
- An additional email blast was sent to student veterans to increase and maintain awareness of our clinical services.
- Three meetings have been held with individual student veteran advisors to gain feedback on various initiatives.
- Forms are currently being finalized and submitted on-line to establish Medicare and VA Choice status
- Several meetings have been held with external and community partners to establish new research and screening partnerships with schools and across the campus.
- Several monthly team meetings were organized and held with the NIC investigators to maintain overall coordination of effort.

Objective 2: Develop a comprehensive panel of objective tests to diagnose mild TBI (mTBI).

a) Hirings:

Two hourly student workers and one graduate assistant were hired since the last report. These
personnel are already working on facilitating the process of recruitment, data collection, and
analysis.

b) Equipment purchased:

- Hardware from Cambridge Electronic Design Ltd, PCB Piezotronics and XPort EMG System has been purchased for the 1st clinical prototype of the BalanceLab apparatus.
- Software development has also progressed to advanced stages. Engineering of software and hardware were developed concomitantly by the same company to effectively secure compatibility of these two system components.

c) Progress towards milestones:

The main objectives for this quarter have been achieved and some excelled. Our continuing studies are on schedule and the following milestones achieved

- Continuing recruitment of subjects, balance, neurocognitive and biochemical data collection, and preliminary data analysis from control and TBI participants.
- Development of the balance system (BalanceLab) continues and the 1st clinical viable prototype is scheduled for delivery in the beginning of the month of February. Based on our experience with this prototype we will be able to further develop its interface, aiming for a user-friendly computational environment.
- Initial processing of plasma samples collected from recruited subjects for miRNA determination.

Objective 3: Develop miRNA inhibitors to reduce neuropathology after TBI.

- a) Hirings:
 - N/A
- b) Equipment purchased:
 - N/A
- *c) Progress towards milestones:*
 - Additional behavioral testing animal use protocol applications are being prepared for review by the University of Montana IACUC.
 - Continued *in-vitro* testing of candidate miRNA agomiRs and inhibitors on 3'-UTR of gene targets to assess activity using luciferase reporter assay.
 - Preliminary study conducted with 16 rats exposed to mild and severe TBI paradigms to assess the effects of TBI on baseline protein and miRNA expression and the efficacy of a novel neuroprotective agent in the lateral fluid percussion animal model.

Objective 4: <u>VAST</u>: <u>Next Generation Learning</u>, Complete the development of a computer-based cognitive training (CCT) system for TBI subjects with cognitive impairment.

- a) Hirings:
 - N/A
- b) Equipment purchases:
 - N/A
- *c) Progress towards milestones:*

VAST Milestones Completed

- Prototype HTML5 mobile app completed, including backend/database and user interface (UI), for mTBI treatment for iOS and Android systems;
- Set of 8 training levels and 40 training exercises for mTBI completed.
- Initial prototype research and testing with 21 subjects completed.

VAST Sub-Tasks Completed

- Comprehensive research into appropriate DT tasks for mTBI. Gathered existing evidence about cognitive impact and effectiveness of exercises, including research of COWAT verbal fluency tests and RUFF figural fluency tests. Developed guidelines for establishing validity of proposed DT exercises in the context of mTBI.
- Pre-clinical testing of small set of DT exercises with mTBI subjects (UM Motor Control Lab)
- 40 distinct DT exercises developed, available in a series of 8 levels.
- Released prototype HTML5 mobile app for testing/training on iOS and Android devices. Frontend designed for cognitive training, including incorporation of levels and progress feedback.
 Back-end for unique scoring and tracking requirements, including collection of data to track user status and progress, with guidelines for improvement.

VAST Progress on Y1 Q3/Q4 Milestones

- R&D into gamification of 8 levels of mTBI divergent thinking training, including intra-exercise scoring feedback necessary for subject engagement and adequate progression through tasks.
- R&D completed of prototype of new variation of figural Trail Making Test as part of figural training package.
- Initiation of research in RUFF figural test as potential component of mTBI training package.
- Enhancement of front-end UI/UX based on user feedback in Q2.
- Initial outreach to identify and secure testing subjects for 8 training levels (mTBI and non-mTBI).

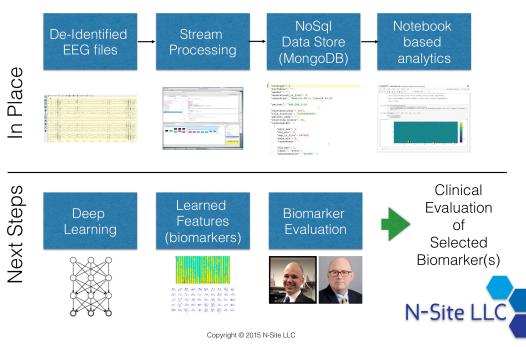
Objective 5: Complete the development and testing of a novel post-traumatic epilepsy diagnostic analysis program.

N-SITE LLC Status Report

Project	01030-MUSRI2015-01, Objective 5
Reporting Period	November 1 2015 – January 31, 2016
Project/Engagement Manager	Alex Philp, Ph.D PI

- a) Hirings:
 - N/A
- b) Equipment purchases:
 - N/A
- *c) Progress towards milestones:*

High Level Dataflow



Quarterly Budget Reports

Objective 1:

MUS MREDI Objective 1 - Operating Statement - Inception to Date

Institution: University of Montana (BMED/NIC)

PI: Dr. Sarjubhai Patel

Banner #: MPHR01

Report Date: 1/27/2016

			Expenses to	
Account	Description	Budget	Date	Remaining
61124	Contract Professional	-	24284.36	
61125	Classified Employee		2455	
61199	Personnel Services-General	145,000.00	26,739.36	118,260.64
61401	FICA	-	1647.32	
61402	Retirement		205.47	
61403	Group Insurance	-	6450.61	
61404	Workers Compensation	-	173.85	
61409	Medicare Tax	-	385.28	
61410	State Unemployment Tax	-	66.87	
61415	TIAA-CREF Retirement	-	2301.97	
61415A	TIAA-CREF 1% HB95	-	242.82	
61499	Benefits-General	72,510.00	11,474.19	61,035.81
62199	Contracted Services-General	23,500.00	-	23,500.00
62208	Laboratory Supplies	-	54.95	
62241	Office Supplies		156.70	
62245	Computer Equipment <\$5,000		2,581.26	
62282	Ink		56.49	
62299	Supplies-General	-	2,849.40	(2,849.40)
62371	Telephone Equipment		53.00	
62382	Data Circuits-Add/Move/Change		42.00	
62399	Communications-General	-	95.00	(95.00)
62401	In State Personal Car Mileage	-	65.07	
62499	Travel-General	-	65.07	(65.07)
	TOTALS	241,010.00	41,223.02	199,786.98

Objective 2:

MUS MREDI Objective 2 - Operating Statement - Inception to Date

Institution: University of Montana (BMED/NIC)

PI: Dr. Sarjubhai Patel

Banner #: MPHR02

Report Date: 1/27/2016

			Expenses to	
Account		Budget	Date	Remaining
	Contract Faculty	-	45,295.58	
	Graduate Teaching Assistant		720.00	
	Student		1,320.00	
61199	Personnel Services-General	167,239.00	47,335.58	119,903.42
61401	EICA		2,685.12	
01.01	Group Insurance	_	4,462.05	
	Workers Compensation	_	307.73	
	Medicare Tax	_	627.99	
	State Unemployment Tax	_	113.24	
	TIAA-CREF Retirement	_	4,289.61	
	TIAA-CREF 1% HB95	_	452.96	
-	Benefits-General	64,397.00	12,938.70	51,458.30
0		0.,007.00	,	52, 155.55
62199	Contracted Services-General	30,000.00	-	30,000.00
62208	Laboratory Supplies	-	7,047.20	
62245	Computer Equipment <\$5,000		186.75	
62249	Minor Software <\$100,000		30,000.00	
62299	General Supplies	25,000.00	37,233.95	(12,233.95)
62304	Postage & Mailing		4.94	
	Communications-General	-	4.94	(4.94)
62701	Buildings & Grounds		427.80	
	Repairs & Maintenance		427.80 427.80	(427.80)
02/99	nepairs & Maintenance	-	427.00	(427.80)
	TOTALS	286,636.00	97,940.97	188,695.03
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MUS MREDI Objectives 3, 4 & 5 - Operating Statement - Inception to Date Includes Subcontracts to VAST (Obj 4) and N-SITE (Obj 5)*

Institution: University of Montana (BMED/NIC)

PI: Dr. Sarjubhai Patel

Banner #: MPHR03

Report Date: 1/27/2016

			Expenses to	
Account	Description	Budget	Date	Remaining
61123	Contract Faculty	-	21,522.06	
61125	Classified Employee	-	32,250.92	
61199	Personnel Services-General	125,422.00	53,772.98	71,649.02
61401	FICA	-	3,036.54	
61402	Retirement	-	1,284.38	
61402C	ORP-Staff TIAA Cref	-	1,415.02	
61403	Group Insurance	-	12,648.46	
61404	Workers Compensation	-	1,371.73	
61409	Medicare Tax	-	710.15	
61410	State Unemployment Tax	-	134.45	
61415	TIAA-CREF Retirement	-	2,056.65	
61415A	TIAA-CREF 1% HB95	-	215.22	
61499	Benefits-General	60,165.00	22,872.60	37,292.40
62147	Subcontract Payments*	-	50,000.00	
62147A	Sub Contract Payments > 25,000*	-	114,190.06	
62195	Professional Services-Internal	-	5.48	
62199	Contracted Services-General	281,000.00	164,195.54	116,804.46
62208	Laboratory Supplies	-	5,987.57	
62208A	Laboratory Supplies - Animals		1,149.95	
62245	Computer Equipment <\$5,000		59.99	
62299	General Supplies	89,945.00	7,197.51	82,747.49
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Subcontract Totals to Date*			
Company	Budget	Expenses to Date	Remaining
VAST (Objective 4)	131,000	41,190.06	89,809.94
N-SITE (Objective 5)	150,000	123,000.00	27,000.00
TOTALS	281,000	164,190.06	116,809.94

556,532.00

248,038.63

308,493.37