

AWARD NUMBER: W81XWH-16-2-0026

TITLE: Legacy Clinical Data from the Mission Connect Mild TBI Translational Research Consortium

PRINCIPAL INVESTIGATOR: Claudia Robertson, MD

CONTRACTING ORGANIZATION: Baylor College of Medicine
Houston, TX 77030

REPORT DATE: July 2018

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE July 2018		2. REPORT TYPE FINAL		3. DATES COVERED 30 Sep 2016 - 31 Mar 2018	
4. TITLE AND SUBTITLE Legacy Clinical Data from the Mission Connect Mild TBI Translational Research Consortium				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-16-2-0026	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Claudia Robertson, MD E-Mail:claudiar@bcm.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Baylor College of Medicine One Baylor Plaza Houston, Texas 77030-3411				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The long-term goal of the Mission Connect Mild Traumatic Brain Injury (mTBI) Translational Research Consortium was to improve the diagnosis and treatment of mTBI. We enrolled a total of 88 mTBI patients and 73 orthopedic injury (OI) control patients into observational studies, and a total of 50 mTBI patients in a clinical trial. The patients were enrolled within 24 hours of their injury, and followed for up to 6 months for the observational studies, and for 3 months for the clinical trial. The data that has been collected as a part of our study is potentially valuable to other investigators because it includes very early assessment of neurological status (within 24 hours of injury) and long-term (6 months) follow-up. The data includes neuropsychological assessment, advanced magnetic resonance imaging, electroencephalogram, and magnetoencephalogram in addition to detailed clinical information about the patient and the injury severity. The goal of the current funding was to submit the clinical data to FITBIR so that it could be made available to other investigators not involved in the project in order to accelerate research.					
15. SUBJECT TERMS Mild traumatic brain injury, MRI imaging, electroencephalogram, magnetoencephalogram, neuropsychological assessment					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	9	19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
1. Introduction.....	1
2. Keywords.....	1
3. Accomplishments.....	1
4. Impact.....	2
5.Changes/Problems.....	2
6. Products.....	3
7.Participants & Other Collaborating Organizations.....	3
8.Special Reporting Requirements.....	4
9. Appendices.....	N/A

1. INTRODUCTION:

The long-term goal of the Mission Connect Mild Traumatic Brain Injury (mTBI) Translational Research Consortium was to improve the diagnosis and treatment of mTBI. The data set resulting from the project was designed and structured to answer the explicit research questions posed in the specific aims of three observational studies and a clinical trial. To accomplish these four specific aims, we planned a single cooperative project, called the Integrated Clinical Protocol. We enrolled a total of 88 mTBI patients and 73 orthopedic injury (OI) control patients into the observational studies, and a total of 50 mTBI patients in the clinical trial. The patients were enrolled within 24 hours of their injury, and followed for up to 6 months for the observational studies, and for 3 months for the clinical trial. The data that has been collected as a part of our study is potentially valuable to other investigators because it includes very early assessment of neurological status (within 24 hours of injury) and long-term (6 months) follow-up. The data includes neuropsychological assessment, advanced magnetic resonance imaging (MRI), electroencephalogram (EEG), and magnetoencephalogram (MEG) in addition to detailed clinical information about the patient and the injury severity. The goal of the current funding was to submit the clinical data to FITBIR so that it could be made available to other investigators not involved in the project in order to accelerate research.

2. KEYWORDS:

Mild traumatic brain injury, MRI imaging, electroencephalogram, magnetoencephalogram, neuropsychological assessment

3. ACCOMPLISHMENTS:

▪ What were the major goals of the project?

Specific aim 1. To format clinical/research data from patients enrolled in our mild TBI studies so that the data can be submitted to FITBIR for sharing with other investigators.

Major Task 1: Project start up. Milestone achieved month 2

Major Task 2: Document, data, and technical preparation. Milestone achieved month 8

Major Task 3: FITBIR form building, data validation, and submission – completed in no cost extension

Major Task 4: Data query and final review. In progress – completed in no cost extension

Major Task 5: Project Close-out. completed in no cost extension

- **What was accomplished under these goals?** All of the forms needed to upload the data were completed, the data was uploaded to FITBIR, and the upload was confirmed to be complete by querying the tables. The data uploaded included the demographic characteristics, injury severity information, the neuropsychological testing that was done, the MRI images, the raw EEG data, and the RAW MEG data.

- **What opportunities for training and professional development has the project provided?**

Nothing to Report

- **How were the results disseminated to communities of interest?**

Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**

N/A

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report

- **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

5. **CHANGES/PROBLEMS:**

Nothing to Report

- **Actual or anticipated problems or delays and actions or plans to resolve them**

N/A

6. PRODUCTS:

The data from the Mission Connect project is now available in FITBIR.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

▪ What individuals have worked on the project?

Name:	Claudia Robertson, MD
Project Role:	PI
Researcher Identifier	ORCID ID/0000-0002-8509-678X
Nearest person month worked:	1
Contribution to Project:	supervised the entire project, facilitated Sierra Fourwind's work to correctly map the clinical data to the FITBIR elements
Name:	Shiny Abraham
Project Role:	Research Coordinator
Researcher Identifier	
Nearest person month worked:	2
Contribution to Project:	Worked with Dr. Robertson and Sierra Fourwinds to coordinate the day-to-day activities of the projects. She has helped Sierra Fourwinds with editing/creating study documents, verifying elements to be submitted, defining the recoding or data transformation that are needed, creation of the FITBIR data forms, and reviewing data that is submitted
Name:	Marianne MacLeod
Project Role:	Research Assistant
Researcher Identifier	
Nearest person month worked:	2
Contribution to Project:	Worked with Dr. Robertson and Sierra Fourwinds to coordinate the day-to-day activities of the projects. She has helped Sierra Fourwinds with editing/creating study documents, verifying elements to be submitted, defining the recoding or data transformation that are needed, creation of the FITBIR data forms, and reviewing data that is submitted
Name:	Brian Biekman
Project Role:	Research coordinator
Researcher Identifier	
Nearest person month worked:	1
Contribution to Project:	Worked with Dr. Wilde to submit the MRI images
Name:	Sierra Fourwinds
Project Role:	PI of Silverwind subcontract
Researcher Identifier	
Nearest person month worked:	2
Contribution to Project:	Responsible for creating the data elements and forms, transforming our data to fit the FITBIR standards, and submitting the data

- **Has there been a change in the active other support of the PD/PI (s) or senior/key personnel since the last reporting period?**

Nothing to Report

- **What other organizations were involved as partners?**

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

N/A

9. APPENDICES:

None