

AWARD NUMBER: W81XWH-17-1-0549

TITLE: Role of Vestibular Hypofunction in Exacerbating Autonomic Dysfunction in Gulf War Illness

PRINCIPAL INVESTIGATOR: Jorge M. Serrador, PhD

RECIPIENT: Veterans Biomedical Research Institute
East Orange, NJ 07018

REPORT DATE: October 2018

TYPE OF REPORT: Annual Report

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			<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
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 Oct 2018	2. REPORT TYPE Annual Report		3. DATES COVERED (From - To) 30 Sep 2017-29 Sep 2018	
4. TITLE AND SUBTITLE Role of Vestibular Hypofunction in Exacerbating Autonomic Dysfunction in Gulf War Illness			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER W81XWH-17-1-0549	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Jorge M. Serrador, PhD Kelly Brewer, MS <u>EMAIL: serradjo@njms.rutgers.edu</u>			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Veterans Biomedical Research Institute 385 Tremont Ave. East Orange, NJ 07018			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 goal of this study is to determine the relationship between vestibular loss and autonomic dysfunction in veterans with GWI, GW era veterans and civilians (Aim 1) and then to determine if improving vestibular function in veterans with GWI will improve their autonomic function.				
15. SUBJECT TERMS NONE LISTED				
16. SECURITY CLASSIFICATION OF: U		17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 12	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	19b. TELEPHONE NUMBER (include area code)	

TABLE OF CONTENTS

Page No.

INTRODUCTION.....	4
KEYWORDS.....	4
ACCOMPLISHMENTS.....	4
IMPACT.....	6
CHANGES/PROBLEMS.....	7
PRODUCTS.....	9
PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS.....	11
SPECIAL REPORTING REQUIREMENTS.....	12
APPENDICES.....	12

1. INTRODUCTION:

The goal of this research is to examine the role of vestibular dysfunction and its effect on autonomic function. Our general hypothesis is that impaired vestibular function causes greater impairments in autonomic function. To examine our hypothesis, we will recruit veterans at both our Rutgers lab and our lab at the VA NJ healthcare system. We will use the Steele case definition to recruit 100 GWI veterans and 50 GW era veterans without GWI.

2. KEYWORDS:

Cerebrovascular, autonomic, vestibular, Gulf War Illness

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

<i>Major Task 1: Establish project management system and training plan.</i>		
Develop protocol, obtain IRB and Human Research Protection Office Approvals	Sep. 2017 - Dec. 2017	50% complete
Train staff on study procedures	Sep. 2017- Dec. 2017	90% complete
Develop and implement recruitment plan: Distribute flyers, recruitment mailings, contact VSOs for outreach assistance	Dec. 2017- Mar. 2019	90% complete
<i>Major Task 2: Determine the relationship between vestibular loss and autonomic dysfunction in veterans with GWI, GW era veterans and civilians</i>		
Screen and enroll participants.	Dec. 2017- Mar. 2019	0% complete
Data analysis.	Jan. 2019- Apr. 2019	0% complete
Publish data.	Apr. 2019- Sep. 2019	0% complete
<i>Major Task 3: Determine if improving vestibular function in veterans with GWI will improve their autonomic function.</i>		
Subsensory galvanic stimulation during vestibular and autonomic testing on subjects with confirmed vestibular hypofunction.	Dec. 2018- Mar. 2019	0% complete

Data analysis.	Jan. 2019- Apr. 2019	0% complete
Publish data.	Apr. 2019- Sep. 2019	0% complete

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

- | |
|---|
| <p>1. Major Activities:</p> <ul style="list-style-type: none"> a) Rutgers University IRB approval on Feb. 7, 2018. b) Rutgers documents submitted to HRPO on Mar. 22, 2018. c) Rutgers HRPO approval obtained June 18, 2018 <p>2. Specific Objectives within this quarter</p> <ul style="list-style-type: none"> a) Obtain IRB and Human Research Protection Office approvals for testing at VANJ. <p>3. Significant Results of Key Outcomes</p> <p>4. Other Achievements</p> |
|---|

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

This project has provided training for research staff to be competent at vestibular and autonomic procedures as well as to be proficient at electrical stimulation procedures.

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report

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

If this is the final report, state “Nothing to Report.”

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- 1) Obtain IRB and HRPO approval to begin study at VANJ.
- 2) Execute recruitment strategy by initiating contact with veterans.
- 3) Begin recruitment and data collection at Rutgers.
- 4) Data analysis.

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS: The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report

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

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Delays in enrollment have been due to the move of our laboratory to a larger facility. This move will enable data collection, however, the setup of specific specialized equipment for testing has been met with unforeseen delays. Equipment is 100% ready by the date of this report and we expect no further delays to our enrollment. Even with these unforeseen delays, we believe that we will be able to meet our recruitment goals within the timeframe allotted.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

There were no changes in expenditures.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals.

No animal use research will be performed to complete the Statement of Work

Significant changes in use of biohazards and/or select agents

No biohazards and/or select agents will be used to complete the Statement of Work

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**
Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Name: Jorge Serrador, PhD

Project Role: PI

Nearest person month worked: 0.5

Contribution to Project: Dr. Serrador has been overseeing all aspects of the project including the human subject’s regulatory requirements including IRB and HRPO submissions. Dr. Serrador is overseeing all aspects of data collection and analysis.

Name: Jie Liu, PhD

Project Role: Post-doctoral Fellow

Nearest person month worked: 0.5

Contribution to Project: Dr. Liu has been developing the protocol for IRB submission at Rutgers University and will be involved in all aspects of data collection, analysis, and publication.

Name: Kelly Brewer, MS

Project Role: Study Coordinator

Nearest person month worked: 0.5

Contribution to Project: Kelly has been generating documents for the VA NJ IRB and HRPO submissions. She has also assisted in training staff on study procedures and will assist in data collection and analysis.

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: N/A

9. APPENDICES: N/A