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TITLE: Identifying Immune Drivers of Gulf War Illness Using a Novel Daily Sampling Approach

PRINCIPAL INVESTIGATOR: Jarred Younger, PhD

CONTRACTING ORGANIZATION: University of Alabama at Birmingham
Birmingham, AL 35294-0111

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14. ABSTRACT Since the last annual report, we have initiated participant screening, participant enrollment and the study protocol. All start up subtasks have been completed. To date 131 potential participants have filled out the online screening questionnaire, seventy of those have been screened by phone, and fourteen have been enrolled in the study. Fifteen participants are scheduled to begin the study protocol in January 2017 and screening for a spring cohort is currently underway. Screening and enrollment will continue as we work toward completing this study.					
15. SUBJECT TERMS Gulf War Illness, cytokines, microglia, daily, immune, phlebotomy, fibromyalgia					
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Table of Contents

	<u>Page</u>
1. Introduction.....	1
2. Keywords.....	1
3. Overall Project Summary.....	1
4. Key Research Accomplishments.....	3
5. Conclusion.....	3
6. Publications, Abstracts, and Presentations.....	3
7. Inventions, Patents and Licenses.....	3
8. Reportable Outcomes.....	3
9. Other Achievements.....	3
10. References.....	3
11. Appendices.....	3

1. INTRODUCTION:

The major aim of this research project is to identify aspects of the immune system that are dysregulated in veterans with Gulf War Illness (GWI). A second aim is to determine whether identified immune system dysregulations are similar to those found in men with Fibromyalgia. To accomplish those aims at UAB, we are recruiting 29 male veterans diagnosed with GWI, as well as 2 healthy veteran controls, and 4 males with Fibromyalgia/Chronic Fatigue Syndrome (FM/CFS). Participants will complete 25 consecutive days of blood draws and provide daily reports of symptom severity. Analyses will then be conducted to identify immune system factors that correlate with day-to-day symptom fluctuations in the participants. Ultimately, this information may be used to develop new treatments that specifically target the pathophysiological mechanisms of Gulf War Illness.

(Note: A complete analyzed data set will consist of the data collected from the 22 participants at Stanford University and the 35 participants at UAB).

2. KEYWORDS:

Gulf War Illness, cytokines, microglia, daily, immune, phlebotomy, fibromyalgia

3. OVERALL PROJECT SUMMARY:

Current Objectives:

- Continue recruitment and data collection at UAB
- Complete the protocol on 35 participants.

Results, Progress and Accomplishments

Task 1: Team review and progress meetings

60% Completed.

(Note: The analysis planning meeting in the revised SOW has been rescheduled to allow time to complete data collection from the 35 participants that will be enrolled at UAB).

Task 2: Submission of Documents for Regulatory Approvals

100% Completed.

Task 3: Start up Machine/Personnel

100% Completed

Task 4: Advertisement

75% Completed. New recruitment tools have been launched and are actively on-going.

Advertisements via the UAB campus/local newspaper and website are on-going.

Radio advertisements were aired May 2, 2016 – May 27 2016 and August 8, 2016 – September 8, 2016, these will resume in 2017. These were an excellent avenue to reach the potential participants.

Task 5: Enroll GWI Participants for Study

35% Completed. Ten GWI participants have been enrolled. We will continue recruitment in January 2017.

(Note: The reported percentage is a representation for the SOW at UAB.)

Task 6: Recruit Control Groups

50% Completed. Will continue recruitment in January 2017, 1 of the 2 healthy controls have completed the protocol and 2 of the 4 Fibromyalgia participants have completed the protocol, the remaining will be enrolled in 2017.

Task 7: Run Protocol

23% Completed. Further progress is dependent on completing Tasks 5 and 6.

Task 8: Quantification of bio-chemicals in blood samples

0% Completed. Further progress is dependent on completing Task 7.

Task 9: Analyses

0% Completed. Further progress is dependent on completing Tasks 7 and 8.

Task 10: Preparation of final report and publications

0% Completed. This task is contingent on completion of Tasks 7, 8, and 9.

Key methodology:

We have used the methodology outlined in other submitted documents. As stated in the SOW, we have recruited participants from a variety of sources, including local advertisements. We have performed the study protocol exactly as described in the SOW. Eight individuals have completed the protocol.

Research Conclusions:

Because we have not completed the data collection, we have nothing to report.

Actual or anticipated problems or delays:

Nothing to report.

Changes to Approach:

We are not proposing any changes to the approach.

KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report.

4. INVENTIONS, PATENTS AND LICENSES:

Nothing to report.

5. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Nothing to report.

6. INVENTIONS, PATENTS AND LICENSES:

Nothing to report.

7. REPORTABLE OUTCOMES:

Nothing to report.

8. OTHER ACHIEVEMENTS:

Nothing to report.

9. REFERENCES:

No references.

10. APPENDICES:

No appendices.