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This project has not yet begun because of major delays in obtaining human subjects approval.

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ANNUAL REPORT

Gulf War Illness: Evaluation of an Innovative Detoxification Program

David O. Carpenter, M.D., Principal Investigator

Introduction:

This project is a pilot study of 50 veterans who suffer from Gulf War Illness. The hypothesis to be tested is that a detoxification program consisting of exercise, sauna therapy and administration of crystalline niacin with nutrient supplements will reduce the symptoms of the Illness and will result in improved clinical chemistry parameters and improved performance on standard cognitive and quality of life tests. The treatment protocol will be administered at the Severna Park Health and Wellness Center, Severna Park, MD. After obtaining informed consent, all 50 subjects will provide blood samples for clinical chemistry measurements and take the cognitive and quality of life tests. Half of the subjects will then enter the detoxification program, which will take about 4-6 weeks. At the end of that period all 50 subjects will repeat the standard tests, with those that did not go through the detoxification program serving as controls for the initial period. The controls will then undergo the detoxification program and at a period of 3 months after completion of the detoxification program, all 50 subjects will provide blood samples and will be given the tests again. The effectiveness of the program will be evaluated by determining whether there has been improved clinical chemistry measures in lipids, glucose and hormones, and whether performance on the cognitive and quality of life tests has improved.

Body:

Unfortunately we have not been able to begin this program. The IRB at the University at Albany approved this project on 4 May 2010, although the PI was not notified of this approval until 29 July 2010. However this approval was withdrawn on 25 August 2010 after additional questions about the project were raised by the USAMRMC. The grant was funded on 27 September 2010 upon receipt of all requested information other than the University at Albany IRB approval.

We then advertized for the Project Coordinator position, and selected Dr. Barbara Tymkiw, M.D., from over 30 applicants and she was placed on our pay role.

On 31 March 2011 we were informed by Email that the University at Albany IRB would not complete their review of this program. They stated that they did not have adequate expertise to review the proposal, and they recommended use of a commercial IRB. This plan was approved by the University at Albany Vice President for Research, who agreed to cover the costs of such a review, and Chesapeake Research Review was selected as the organization to perform the review. Because of the long expected delay, Dr. Tymkiw was placed on leave of absence without pay on 1 July 2011 She has been the only person who has received salary from the grant to date.

USAMRMC staff then raised the concern the Food and Drug Administration approval might have to be obtained for the treatment protocol. Therefore on 27 September 2011 a request was submitted to the FDA that our protocol be determined to

be exempt from the requirement for review as a "investigational new drug", and on 29 September 2011 that request was granted in an Email from Dr. Shaw T. Chem, Deputy Director, Office of Drug Evaluation IV, FDA.

As advised by Ms. Lori Walther, we are at present waiting for additional comments on our protocol from the USAMRMC before submitting the full protocol for review by the Chesapeake Research Review panel. We hope that this can be accomplished in a matter of weeks.

Key Research Accomplishments:

None

Reportable Outcomes:

None

Conclusions:

The project has been delayed because of the refusal of the University at Albany IRB to perform the required review. However very few funds have been expended and we hope to obtain IRB approval in the future using a commercial IRB group. If and when IRB approval is obtained we hope to begin the project and will request a no-cost extension so as to complete it as proposed.