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Hyperbaric Oxygen therapy in the Treatment of Chronic Mild-Moderate Blast-Induced Traumatic Brain Injury PCS and PTSD

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<b>13. SUPPLEMENTARY NOTES</b>					
<b>14. ABSTRACT-</b> The purpose of the study is to see if a four-week course of forty low-pressure HBOT's can significantly improve symptoms and cognitive function in military veterans with mild-moderate blast-induced TBI/PCS with PTSD. The scope of the project is to recruit, enroll, treat, and test 50 subjects in a randomized controlled double-blind study within 18 months. There are no results to report at this time since the study has not begun. The study is still in the pre-enrollment regulatory process. Pre-IND meeting was held with the FDA on 3/12/2012. Recommendations were made regarding change in study design, screening, and outcome instruments for a study whose results, if positive, would be suitable for a new pre-market FDA application. These recommendations prompted sourcing for additional funding and partner sites. An additional site has been recruited and administrative organizational meetings held to secure funding for the additional site. A final protocol will be agreed upon in the next week and the IND application prepared for submission.					
<b>15. SUBJECT TERMS-</b> HBOT: hyperbaric oxygen therapy; TBI: traumatic brain injury; PCS: post-concussion syndrome; PTSD: post-traumatic stress disorder					
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### I. INTRODUCTION

Mild-moderate blast-induced traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) affect 11-28% and 13-17%, respectively, of U.S. combat troops returning from Iraq and Afghanistan. Evidence-based medicine exists for PTSD, but there is no effective treatment for the post-concussion syndrome (PCS) of mild-moderate TBI nor the combined diagnoses of PCS and PTSD. Between the Fall of 2008 and end of 2010, we conducted a pilot trial of hyperbaric oxygen therapy (HBOT 1.5 atmospheres absolute) in military veterans with both TBI/PCS and PTSD and achieved substantial symptomatic and cognitive improvements. Preliminary results were published 11/2011 in the Journal of Neurotrauma (<http://www.liebertonline.com/doi/abs/10.1089/neu.2011.1895>). The purpose of the proposed study is to see if a four-week course of forty low-pressure HBOT's can significantly improve symptoms and cognitive function in military veterans with mild-moderate blast-induced TBI/PCS with PTSD. The scope of the project is to recruit, enroll, treat, and test 50 subjects within 18 months in a randomized controlled double-blind study.

### II. BODY

The research accomplishments associated with the tasks in the Statement of Work are as follows:

**A. Obtain IRB approval prior to award date:** IRB approval was obtained from LSU School of Medicine 12/10/2010. VA IRB approval was not obtained until ORP approval could be secured. Second level ORP approval was held pending FDA IDE procurement. FDA Pre-IDE Request from the fall of 2009 was lost at the FDA. The FDA re-instituted the pre-IDE application in the summer of 2010 and a decision was issued in 5/2011 diverting the P.I. to the FDA Center for Drug Evaluation and Research. The P.I. requested a face-to-face Pre-IND meeting with the FDA that was granted 11/2011. The meeting was held on 3/12/2012.

**B. Recruit sufficient numbers of appropriate subjects to complete the study within project period:** The study is still in the pre-study regulatory approval process. No recruitment has occurred.

**C. Enroll, test, and treat 50 subjects within 17 months from award date:** The study is still in the pre-study regulatory approval process. No enrollment has occurred.

**D. Analyze data and submit a manuscript for peer-reviewed publication within 24 months of funding:** The study is still in the pre-study regulatory approval process. No data has been generated.

III. KEY RESEARCH ACCOMPLISHMENTS

There are no key research accomplishments since the study has not begun.

IV. REPORTABLE OUTCOMES

There are no reportable outcomes since the study has not begun.

V. CONCLUSION

The study is still in the pre-approval regulatory stage. Pre-IND meeting was held at the FDA on 3/12/2012. Recommendations were made to change the study design, screening instruments, and outcome instruments to accommodate a pre-market application for a new indication for hyperbaric oxygen therapy. The recommendations required a larger number of subjects for the study and recruitment of at least one additional site. The P.I. has recruited an additional site that will double the number of subjects. The P.I. has also held administrative and planning meetings to seek additional funding and agree on a final protocol. The protocol/instruments will be approved next week and the IND application process begun.

VI. REFERENCES

There are no references.

VII. APPENDICES

There are no appendices.

VIII. SUPPORTING DATA

There is no supporting data.