



The University of Oklahoma

Health Sciences Center

COLLEGE OF PUBLIC HEALTH

April 17, 2013

Dr. William Duncan
 Vice President for Development
 International Hyperbaric Medical Foundation
 8210 Cinder Bed Road Ste C-3
 Lorton, VA 22079-1135

Re: The Oklahoma Veterans Recovery Plan (OKVRP)

Dear Dr. Duncan

The purpose of this letter is to indicate the strong support of the College of Public Health at the University of Oklahoma Health Sciences Center (OUHSC) to reduce the burden of disease and improve the outcomes of Oklahoma veterans with traumatic brain injury/post-concussion syndrome. We are pleased to indicate our commitment to partner in this effort through the Oklahoma Veteran's Recovery Plan.

The College of Public Health is one of only 50 accredited schools of public health in the United States. The College, through its Department of Biostatistics and Epidemiology, will provide services as a contractor to support the data management and statistical analysis of the data collected through the OKVRP, and will advise on the scientific interpretation of the results obtained. This effort is directly in line with the Department's mission, which includes serving State, community and private entities by providing biostatistical and epidemiological support for projects and programs that involve clinical and/or population health data. The Department has faculty biostatisticians, data management and computer programming staff, and graduate research assistants to assist in providing the services needed by the OKVRP. It also has the necessary computer hardware and software to fully meet the needs of the OKVRP. This includes computer server space that is maintained and administered according to policies and procedures related to electronic storage of protected health information, security, and electronic back-up by the OUHSC Information Technology Department.

The OKVRP is facilitating the access of Oklahoma veterans to the nationwide study, NBIRR-01 of the International Hyperbaric Medical Foundation. This study is a prospective registry of patients (veterans) with traumatic brain injury who are treated with hyperbaric oxygen therapy, to document their short and long-term health outcomes, as well as several important occupational, social, and cost outcomes. A strength of the registry is the use of the standardized neuropsychological assessment test, ANAM, which evaluates the speed and accuracy of attention, memory, and thinking ability. This test was administered to most veterans prior to their deployment and provides a standardized pre-injury baseline assessment from which to evaluate the effect of treatment. In addition, the OKVRP will measure and analyze a number of other important clinical and public health outcomes, including medication use, career and employment outcome, and health economic outcomes.

College of Public Health ... promoting healthier tomorrows through education and research today.

Dr. William Duncan

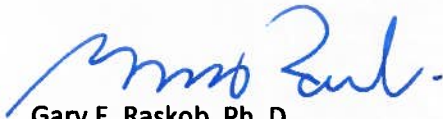
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Although the randomized clinical trial is the most definitive scientific method to evaluate a treatment, it is my professional judgement, as a clinical epidemiologist with more than 25 years of experience in the design and conduct of clinical trials, that a randomized trial is not feasible at the present time for hyperbaric therapy of traumatic brain injured veterans. The reasons are: (a) the documented poor prognosis and high rates of serious long-term outcomes of significant traumatic brain injury/post-concussion syndrome in veterans treated with current standard therapy, (2) the high unmet need for a more effective therapy, (3) the relative safety of hyperbaric oxygen therapy when given by qualified personnel, and (4) the dramatic results observed with hyperbaric oxygen therapy in selected patients and some case series of patients. Because there is a relative low risk from hyperbaric oxygen therapy, most patients wish to at least try it to improve their outcome and life. Consequently, it will not be feasible to enroll patients in a randomized trial due to the frequent lack of consent to receive the control (standard) therapy. The use of a prospective treatment registry, as will be done in the OKVRP, is an appropriate step in such circumstances, and will provide important information about the outcomes of therapy, and its risks and costs, while at the same time, offering the potential for some benefit of this therapy to all of the patients. The results obtained will also be helpful to plan future research, in which the randomized trial design can be utilized, to "fine tune" the therapy to potentially improve its effectiveness, safety, and efficiency (for example, whether 40, 60 or 80 treatment sessions are needed).

In conclusion, the OKVRP is an important project that will provide key scientific information about a therapy with the potential to improve the health and life outcomes of thousands of Oklahoma veterans who have suffered traumatic brain injury. The College of Public Health provides its strong support and will be pleased to work with the International Hyperbaric Medical Foundation and other partners in this effort. If any further information is needed, please do not hesitate to contact me.

Sincerely,



Gary E. Raskob, Ph. D.

Dean, College of Public Health

Professor, Epidemiology and Medicine

University of Oklahoma Health Sciences Center