Trustees of Dartmouth College
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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CPHS APPROVAL OF SUBMISSION

August 30, 2019

Jay Buckey
Biomedical Research

CPHS #:	STUDY00024438	Action:	Approved
Principal Investigator:	Jay Buckey	Action Date:	8/30/2019
Submission Type:	Modification/Update	Expiration Date:	6/19/2020
Review Type	Expedited		
Funding:	• Medicine Administration		
Title of Study:	Multicenter Registry for Hyperbaric Oxygen Therapy		
Risk Level:	No greater than minimal risk		
Notes:	-Consent waived per 45 CFR 46.116(d). -Authorization waived per 45 CFR 164.512(i)(2)(ii). -Future research projects utilizing this data repository must be sent to CPHS for review referencing the CPHS approval number of the data repository. For long term follow up option: -CPHS determined this research involving minors to be research not involving greater than minimal risk as per 45 CFR 46.404 and 21 CFR 50.51. -CPHS determined this study, which enrolls individuals with impaired decision-making capacity, not to involve experimental treatment. The Committee approved the enrollment of individuals with impaired decision making capacity when surrogate consent can be provided by a durable power of attorney for health care, court appointed guardian, or next-of-kin. ***The long term follow-up option will only occur at Dartmouth Hitchcock Medical Center as a pilot program at this time.**		
Modifications:	Clarification regarding where the long term option to the study will be taking place, addition of funding and study personnel changes.		
Documents Reviewed:	• CPHS_research-use-of-info-or-specimens_28Aug2019.docx • DEPARTMENT of MEDICINE DONOR and DISCRETIONARY FUNDS APPLICATION_HBO Registry.pdf		

The Committee for the Protection of Human Subjects has approved this submission. Approval by CPHS is based on the study's appropriate balance of risk and benefit to subjects, a study design in which risks to subjects are minimized, and a determination that the criteria for approval at 45 CFR 46.111 and 21 CFR 56.111 are satisfied as appropriate.

This submission has received Expedited review based on the federal regulation(s):

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Informed consent is a process beginning with a description of the research and including an evaluation of comprehension by the researcher. Once the consent form has been signed, each participant should receive a copy. Assessment of each participant's consent by the researcher should continue throughout a research study.

Go to the documents tab in this study in Rapport to download the stamped approved consent form.

CPHS approval of this study expires on 6/19/2020. You are required to submit a continuing review at least 30 days before expiration or study closure. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

Any modification to previously approved materials must be approved by the CPHS prior to initiation. You can submit a modification by navigating to the active study and clicking Create Modification / CR.

Navigate to the active study and click "Report New Information" to report unanticipated problems involving risks to subjects or others, as well as certain adverse drug events and medical device effects. In addition, please promptly report any known instances of noncompliance and complaints.

If you have any questions, please direct them to CPHS.Tasks@Dartmouth.edu.

Sincerely,

Rachel D. Bibeault, CIP
Senior Human Research Analyst
Committee for the Protection of Human Subjects

cc: Abigail Fellows