



USF HEALTH HYPERBARIC OXYGEN THERAPY CENTER

# ANNUAL REPORT

JULY 1, 2024 – JUNE 30, 2025

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“HYPERBARIC OXYGEN TREATMENT FOR VETERANS WITH TRAUMATIC BRAIN INJURY”

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# USF HEALTH HYPERBARIC OXYGEN THERAPY (HBOT) CENTER EXECUTIVE SUMMARY JULY 1, 2024 – JUNE 30, 2025

## I. EXECUTIVE SUMMARY

The University of South Florida (USF) Health Hyperbaric Oxygen Therapy (HBOT) Center successfully concluded the second of five years of their landmark, state-funded clinical trial. The study is evaluating the efficacy of HBOT on symptoms of traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) in Florida’s veterans and active-duty service members.

Supported by a \$28 million appropriation from the Florida Legislature, this initiative represents the most rigorous hyperbaric research effort in the nation specific to TBI. Participant enrollment officially began in December 2024, marking the operational launch of Florida’s first university-based hyperbaric research center dedicated to veteran brain health. The FY2025 reporting period (July 1, 2024 – June 30, 2025) therefore, reflects the first six months of clinical operations and initial productivity.

While the study’s overall enrollment target of approximately 420 participants may appear modest relative to its’ investment, this scale reflects the extraordinary intensity, duration, and regulatory rigor of the research. Each participant commits to 40 hyperbaric oxygen treatments (“dives”) delivered in less than 12 weeks, with each study visit lasting between 90 minutes to 2 hours, some sessions are followed by comprehensive clinical and research evaluations. This sustained commitment, combined with the individualized oversight required for an FDA Investigational New Drug (IND) protocol, accounts for the study’s four-year duration and the necessity of constructing a dedicated hyperbaric research facility to ensure uniformity, safety, and scientific validity across all sessions.

Building on this foundation, five complementary sub-studies were developed alongside the main clinical trial to maximize translational value and scientific rigor (Audiology, Blood Biomarkers, EEG, fMRI, Microbiome, and Sleep) seek to identify biological correlates of recovery, recognizing that agencies such as CMS and FDA will require quantifiable biomarkers in addition to psychological outcome measures when evaluating HBOT’s therapeutic value for TBI. A sixth sub-study, Medical Anthropology, examines how the intensity of HBOT participation affects real-world feasibility, family dynamics, and perceived benefits. Together, these components create a comprehensive framework designed not only to evaluate safety and efficacy but also to inform national policy discussions on coverage, access, and long-term implementation of HBOT for veteran brain health.

## By the Numbers

- 471 Veterans expressed interest statewide
- 148 consented; 78 completed full baseline screening
- 45 randomized into treatment; 27 completed the full treatment protocol
- 18 dropouts overall (2 during treatment; 16 during screening)
- 100% retention, >95% active-cohort retention, zero safety events
- 20 new jobs created; 8 held by veterans or military spouses
- Participants representing 30+ Florida counties; average one-way commute ~47 miles (median ~35 miles; range 6-95 miles)
- 6 translational sub-studies activated
- 6 Sechrist monoplace chambers in operation; 24 daily dives on a single 8-hour shift

## Financial Summary at a Glance

- Total Appropriation: \$28,000,000
- Cumulative Expenditures (FY2023-FY2024): \$9,062,380.92
- FY2025 Expenditures: \$4,156,849.92
- Remaining Reserves: \$18,937,619.08

## Operational and Translational Progress

Operating within the regulatory framework of FDA IND #172640 (ClinicalTrials.gov NCT06581003), the Center leverages a multidisciplinary team spanning Anthropology, Emergency Medicine, Neurosurgery, Medical Engineering, Otolaryngology, the Office of Clinical Research, and USF Health Core Facilities. Six Sechrist monoplace chambers (three 3600H and three 3300H) support approximately 24 daily dives with full standard operating procedures (SOP) adherence and zero safety events reported during FY2025. Neuropsychological assessment functions as a primary evaluation arm, complemented by six activated sub-studies (Blood Biomarkers, EEG, fMRI, Microbiome, Qualitative Medical Anthropology, and sleep/wearables) that strengthen scientific rigor and Florida's return on investment (ROI) by generating publishable, federally competitive data capable of informing national policy discussions on HBOT access and coverage.

## Collaborative Reach

The HBOT Clinical Trial is supported by a robust network of institutional and industry collaborators, each contributing specialized expertise to ensure scientific rigor, regulatory compliance, and operational excellence.

- *Cortechs.ai*: Provider of NeuroQuant® volumetric imaging software supporting quantitative assessment of structural brain changes over time.

- *Duke University Phase I Biomarker Laboratory*: Supporting longitudinal analysis of inflammatory and neural repair markers.
- *Global Clinical Intelligence (GCI Health)*: Developer of a secure, HIPAA-compliant data management platform used for electronic consent, participant tracking, integration with Ripple Science, enhancing transparency, scheduling efficiency, and protocol compliance across all HBOT study operations.
- *Omniscient Neurotechnology America LTD*: Developer of Quicktome® Connectomics Suite (FDA-cleared, AI-based brain mapping) enabling advanced visualization and quantification of functional connectivity and neural repair.
- *Oura Health Ltd*: Provider of the FDA-registered Oura Ring Gen 4 wearable device used for continuous physiological and sleep monitoring, advancing translational research on recovery, circadian rhythm, and autonomic function.
- *Ripple Science, Inc.*: Cloud-based clinical research management system (Ripple Platform) supporting participant scheduling, workflow tracking, and communication between research staff and veterans to ensure seamless coordination across all study sites and sub-studies.
- *Sechrist Industries, Inc.*: Manufacturer and technical service provider for USF Health's six monoplace hyperbaric chambers, ensuring operational safety and reliability.
- *Tampa VA Research & Education Foundation (TVAREF)*: A nonprofit Veteran Affairs research corporation facilitating collaboration between USF and the James A Haley Veterans' Hospital. TVAREF supports veteran recruitment, regulatory coordination, and data integration between VA and USF research teams.
- *USF Health Core Facilities*: Institutional collaborators providing specialized infrastructure and technical support through the Biorepository, Center for Microbiome Research, fMRI Research Core, Research Methodology & Biostatistics Core ensuring standardized data collection, analysis, and biobanking across sub-studies.

Together, these partnerships establish a public-private research ecosystem that connects Florida's investment in veteran brain health to national networks of scientific and technological innovation. This integrated model ensures that data generated through the HBOT Clinical Trial meets the highest federal standards while positioning the State of Florida and USF Health as leaders in precision neurorehabilitation research.

## **Veteran Workforce and Engagement**

The HBOT Center prioritizes veteran and military spouse employment. Twenty positions have been created to date; eight are filled by veterans or military spouses. Veterans caring for veterans is a theme that appears to resonate well with our participants. There is an inherent trust when our team screens applicants and subsequently ensure their safety throughout the trial. We will explore whether this assumption merits any validity as it relates to high adherence rates.

## II. FINANCIAL SUMMARY

During FY2025, the USF HBOT Center maintained strong fiscal stewardship and strategic resource allocation. Expenditures for the period totaled \$4.16 million (14.9%), primarily supporting facility operations, workforce, safety compliance, and ongoing vendor and software contracts that sustain research activities. These investments ensured streamlined clinic operations, participant engagement, and data integrity across all active sub-studies. With \$18.94 million remaining in reserves, the program remains fully funded through FY2028, positioned to support continued research, dual-shift expansion, and long-term sustainability planning.

### 1. Fiscal Overview

Category	FY2025 Expenditures (\$)	Purpose
Facility Operations	\$1,037,184.76	Utilities, insurance, custodial, and environmental services for HBOT Center operations.
Equipment Maintenance & Safety	\$848,707.24	To ensure continuous chamber functionality, preventive maintenance, and environmental safety compliance.
Capital Equipment	\$10,957.00	Interacoustics Titan V2 Tympanometer acquisition supporting the Audiology sub-study
Salaries & Fringe	\$1,040,000	Salaries and Fringe for HBOT research and clinical staff
Contractual Services	\$624,739.69	External vendor agreements, Sechrist, consulting, and research support services.
Software & Data Systems	\$480,000	Includes software systems used for participant recruitment and consent, marketing and communications, and data analysis.
Consumables and Research Support	\$115,218.23	Veteran reimbursement for time and travel under main trial and sub-studies.
Total FY2025 Expenditures	\$4,156,849.92	

## III. PARTICIPANT METRICS

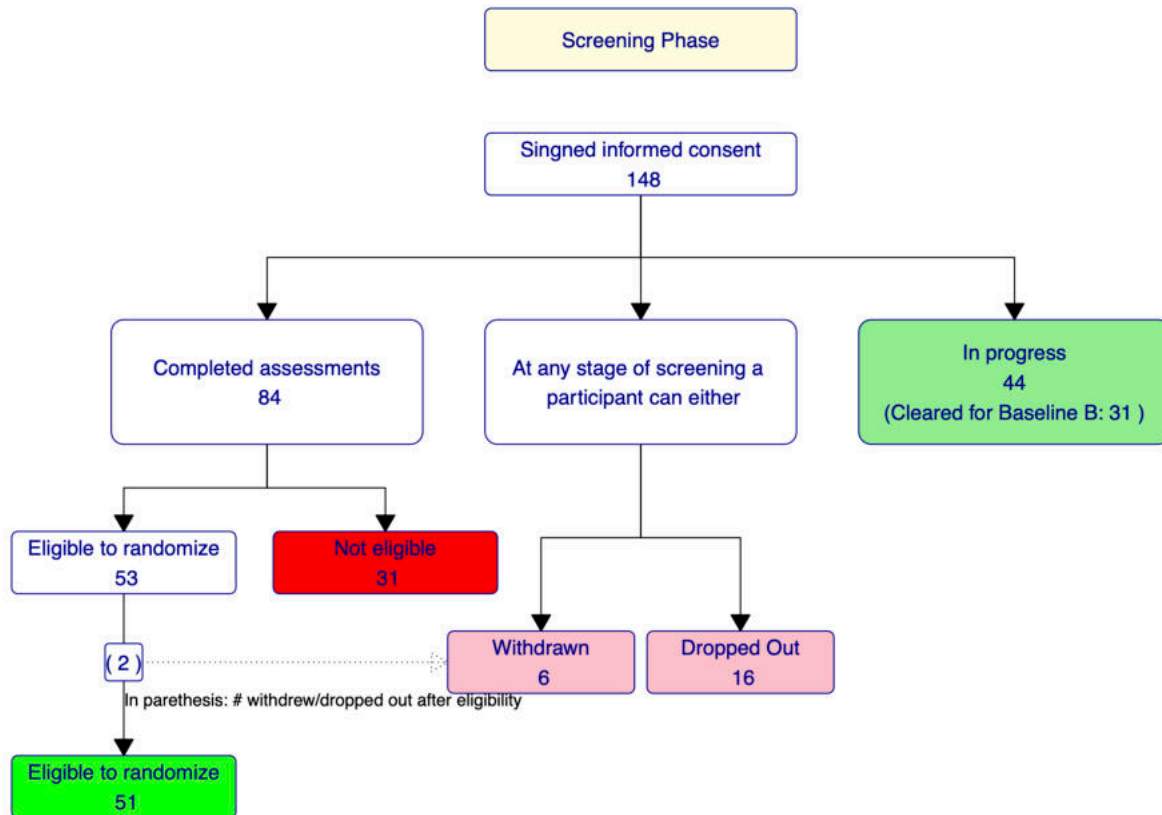
In FY2025, the USF Health HBOT Center advanced its clinical trial implementation maintaining a 100% participant retention rate with no dropouts. A total of 471 veterans expressed interest,

123 provided consent, 78 completed full eligibility screening, and 38 were randomized into the treatment phase. The Center operates a single, daily shift using six Sechrist monoplace hyperbaric chambers. Planning for a dual-shift operational expansion is underway for FY2026 to increase capacity and reduce scheduling bottlenecks.

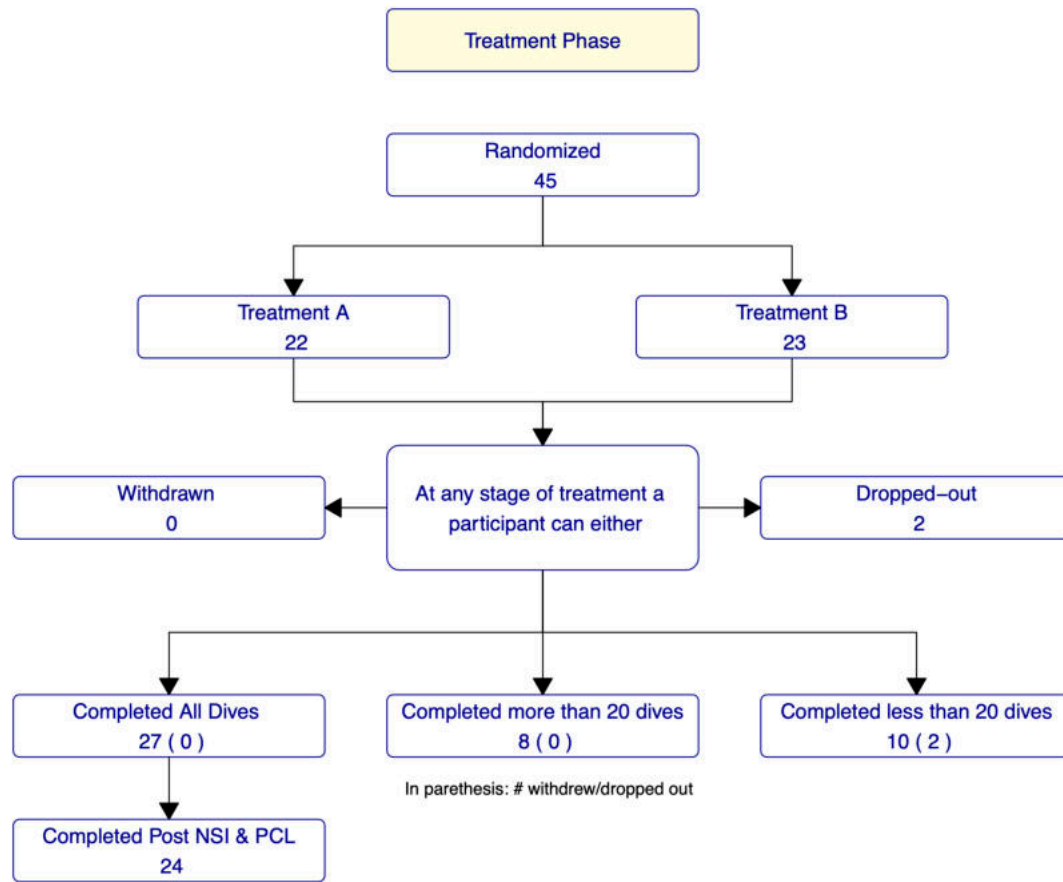
## A. Enrollment Overview

Category	N
Consented	148
Completed Baseline A	78
Completed Baseline B	53
Randomized	45
Completed Rx	27
Drop-out	18
Withdrawn	6
Not Eligible	31
Withdrawn before randomization	6

### Screening phase



## Treatment phase



## B. Participants Consented for Sub-Studies

Sub Study	Consent
Oura Ring	145
EEG	145
Stool sample	139
Blood banking	126
fMRI	132

## C. Participant Demographics

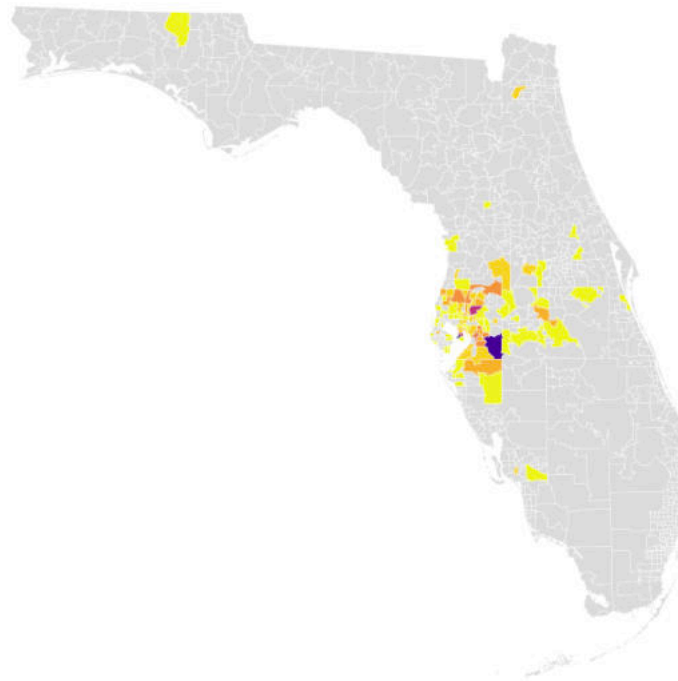
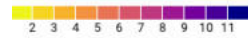
	Overall
	(N=140)
<b>Age (years)</b>	
Mean (SD)	47.7 (11.0)
Median [Min, Max]	47.3 [0, 75.8]
<b>Sex</b>	
Female	26 (18.6%)
Male	114 (81.4%)
<b>Race</b>	
Asian	2 (1.4%)
Black or African American	8 (5.7%)
Native Hawaiian / Pacific Islander	1 (0.7%)
Other	5 (3.6%)
Refuse	2 (1.4%)
Two or more	11 (7.9%)
White	111 (79.3%)
<b>Ethnicity</b>	
Hispanic	26 (18.6%)
Non-Hispanic	114 (81.4%)
<b>Military Branch</b>	
Air Force	21 (15.0%)
Army	60 (42.9%)
Army, Marines	1 (0.7%)
Army, Navy, Reservist or National Guard	1 (0.7%)
Army, Reservist or National Guard	4 (2.9%)
Coast Guard	2 (1.4%)
Marines	18 (12.9%)
Marines, Other	1 (0.7%)
Navy	24 (17.1%)
Navy, Marines	1 (0.7%)
Navy, Reservist or National Guard	1 (0.7%)
Reservist or National Guard	2 (1.4%)
Missing	4 (2.9%)

## D. Geographic Reach

Interest in the HBOT Clinical Trial is statewide, with veterans from more than 30+ counties in the program. The average one-way commute is ~47 miles reflecting strong commitment among Florida veterans to participate in the research project. Heat maps of interest and active enrollment show the highest concentrations across Central and West-Central Florida, with representation extending across the Panhandle and South Florida. Each veteran's commitment to 40 hyperbaric treatments over approximately 12 weeks underscores both the rigor of the protocol and the dedication of Florida's veterans to advancing this research.

### Geographic Distribution of Enrolled Participants

Total enrolled (consented) participants in the USF Health HBOT TBI clinical trial for Veterans and active-duty service members, as of 20-AUG-2025, by residential ZIP code in Florida.



Participant distribution by residence: Florida (n = 195) and out-of-state (n = 8); total N = 203.

Map: Joanna Gonzalez, BS, BS – Clinical Research Associate • Source: Internal study records – USF Health, Morsani College of Medicine • Map data: © Esri, TomTom North America, Inc., United States Postal Service • Get the data • Created with Datawrapper

Residential distribution of veterans who expressed interest in the HBOT Clinical Trial across Florida. Darker shading indicates greater interest density by Zip Code.

<https://datawrapper.dwcdn.net/JncLY/4/>

## E. Economic and Workforce Impact

a. *Florida Jobs Created:* New Florida jobs created (to date): 20 (of which 8 are filled by veterans or military spouses).

b. *Veteran and Military Spouse Employment*

Role	# of Veteran/Military-Affiliated Staff	Source Program
HBOT Technicians and Safety Personnel	5	Airforce, Army, Navy, Royal Navy
Clinicians	1	Airforce
Research Coordinators	2	Airforce, Army



## IV. A RECAP OF CLINICAL TRIAL ACHIEVEMENTS PRIOR TO JULY 1, 2024

In June 2023, the Florida state legislature appropriated \$28M to USF Health for the purpose of exploring Hyperbaric Oxygen Therapy (HBOT) as a treatment for mild-moderate traumatic brain injury (TBI) in our Veterans population. Initiated by former Speaker of the Florida House of Representatives, Senator Paul Renner, this grant enabled USF Health to execute the most comprehensive, rigorous study of its kind. Harry van Loveren, MD, Chair of the Department of Neurosurgery, serves as the Principal Investigator, which makes him responsible for study design, budget oversight, and final deliverables (e.g. results).

Prior to receiving this award, Dr. van Loveren collaborated with two basic scientists from within his department to formulate a hypothesis and potential study design. This proposal was then submitted for review and funding support to the state legislature in accordance with all applicable rules. Upon receiving budget approval, Dr. van Loveren immediately called for a series of round table discussions to solicit “the best of” recommendations.

Participants in the early meetings represented different stakeholders or content experts. Researchers exposed us to varied TBI measures; HBOT experts helped us understand facility requirements; biostatisticians provided study design validation; former and current military shaped enrollment potential; and administrators ensured fiscal integrity. Over the course of multiple discussions during the first quarter of funding, there were five key takeaways:

1. We have a duty to explore as many legitimate biomarkers as possible to maximize the ROI of the grant, including a qualitative study for health policy decision-making.
2. We need a double-blind, randomized study design of 420 participants to have statistically significant results.
3. We want to focus on local (within 60-minute drive) participants to minimize external variables influencing behavioral changes.
4. We want some form of reimbursement to participants for their time & effort, including funds for placebo arm participants to receive actual treatment if desired.
5. We need full control of our own facility to ensure all treatments, including placebos, are run to the exact same protocols.

With these five standards established, phase two of our project commenced. The primary measures (neuropsychology testing) and six sub-studies (sleep, hearing, EEG, brain imaging, microbiome, and blood) initiated written protocols including hypotheses, literature reviews, and budgets. Concurrently, our HBOT consultants were contracted to work with USF Health facilities on securing a location for the new Center followed by contracts for engineering, design, equipment (e.g. chambers, compressors, etc.), and technology.

Dr. van Loveren remained personally involved in all scientific and facility conversations relying heavily on expert opinions for his own decision-making. As the Center construction commenced, one of the primary questions needing answers was staffing requirements. We wanted to exceed minimum safety standards (as designated by accreditation boards) and partnered with the USF Emergency Medicine department to include an MD-level Safety Director and APP support. Additional staff included hiring and training technicians, who would operate the chambers themselves.

A separate component to the HBOT study that is often understated is the marketing efforts. Attracting over four hundred volunteers is an incredibly difficult task, which our partners at the VA and other University studies found overwhelming. In addition to the volume of needed participants is their retention—40 dives over the course of three months—not including screening or post testing periods. Our multidimensional marketing campaign includes social media, personal emails, website development & maintenance, radio adverts, community events, and simple word-of-mouth. Strategic planning began in early 2024 for the planned launch of that summer.

Although the HBOT Center opening was delayed due to an historic hurricane season, our six-chamber facility welcomed its first wave of divers in November 2024 to great aplomb. The facility design included a reception room, locker areas for changing, restrooms, clinic space, and dedicated offices for confidential work.

Successfully running a program that is as complicated and unique as the USF Health HBOT study requires constant attention and maintenance. The learning curve is incredibly steep, which is why we keep regular meetings for the scientific committee, sub-study groups, operations, and facilities. The success of our efforts is not any single person; rather, it is the collective, collaborative efforts of over 50 team members contributing from departments and offices across the greater University and advisors beyond main campus.

## V. STATEWIDE AND INSTITUTIONAL IMPACT

### A. Statewide Reach & Veteran Engagement

At the outset of the HBOT Clinical Trial, the study team anticipated that recruiting veterans with a history of mild-to-moderate TBI and PTSD could pose challenges due to the sensitive nature of these conditions, geographic dispersion, and competing treatment priorities. Instead, Florida's veteran community has shown remarkable enthusiasm and commitment. Florida's \$28 million legislative investment continues to demonstrate measurable return through statewide engagement, veteran employment, and the creation of durable, FDA-regulated infrastructure for translational breadth. Within the first six months of operations, more than 470 veterans across 30 Florida counties expressed interest in participation, far exceeding projections and demonstrating the strength of community awareness and trust in this state-supported initiative.

This success reflects a deliberate, multi-platform recruitment strategy supported by Ripple, REDCap, and eFlorence, three integrated systems that ensure seamless participant tracking, data accuracy, and regulatory compliance. Ripple manages outreach and participant coordination, REDCap captures clinical outcomes in a secure, 21 CFR Part 11-compliant environment, and eFlorence maintains centralized regulatory and study documentation under FDA and IRB oversight. Together, these systems form the digital backbone of the study's operational infrastructure, supporting transparency, audit readiness, and data integrity across all phases of research.

Complementing this infrastructure, GCI Health led a statewide media and digital campaign that amplified awareness through radio, social media, and veteran networks, reaching thousands of Floridians. Additionally, a collaboration with the James A Haley Veterans' Hospital established a direct referral and data-coordination pathway, allowing veterans identified through VA channels to receive standardized information, streamlined eligibility screening, and coordinated follow-up. This partnership ensures recruitment integrity and strengthens engagement across Florida's veteran network.

Equally vital to the study's success is its "Veterans Serving Veterans" employment model, which has created twenty dedicated positions, eight of which are filled by veteran or military spouses. This model integrates lived experience into the heart of clinical operations, creating relatability and mutual trust between staff and participants. By employing veterans to serve other veterans, the Center has helped break down longstanding stigmas surrounding mental-health discussions and TBI-recovery; encouraging participants to share openly, adhere to study protocols, and take an active role in their rehabilitation journey. The result is a unique environment of compassion, accountability, and shared purpose that distinguishes Florida's HBOT initiative nationally.

Through the integration of Ripple, REDCap, and eFlorence, combined with statewide partnerships and veteran-led staffing, the HBOT Clinical Trial has established a scalable, veteran-centered model for FDA-regulated research that other states can emulate.

## **B. Academic and Clinical Integration**

Florida's investment in the USF Health HBOT Center continues to generate lasting institutional and statewide benefits. A cornerstone of this growth is the collaboration between USF Health and its primary teaching hospital, Tampa General Hospital (TGH). Within the forthcoming TGH Surgical, Neuroscience & Innovation Tower, scheduled for completion in FY2028, the TGH Neuroscience Institute is discussing the introduction of a new hyperbaric-medicine program featuring one multiplace and two monoplace hyperbaric chambers.

This initiative is being developed in close coordination with the HBOT Center's Operations team to establish a dual-use model, combining commercial clinical operations with a translational research platform, a structure that will allow the facility to serve both patient care and scientific discovery needs. As part of its long-term vision, USF Health is developing a commercialization and

accreditation roadmap that positions the HBOT Center as a UHMS-accredited ambulatory research and clinical facility, helping ensure statewide access to evidence-based hyperbaric care.

The anticipated TGH hyperbaric program will expand access to FDA-cleared indications that are highly relevant to the Neuroscience Institute's clinical and research portfolio, such as the management of radiation-induced tissue injury including head, neck, and brain necrosis, chronic refractory osteomyelitis affecting cranial or spinal structures, and central nervous system infections or abscesses where oxygen therapy enhances antimicrobial efficacy. It will also support treatment of emergent neurological conditions including cerebral air embolism and carbon-monoxide poisoning, as well as ischemic and wound-healing disorders that influence neural and musculoskeletal recovery.

As a Level I Trauma Center, TGH's planned inpatient multiplace chamber positions it as one of the few Florida sites capable of managing complex dive-related and decompression injuries, expanding rapid-access care for veterans and service members statewide. This capability directly benefits Florida's veteran and active-duty populations, providing specialized access for service members with blast injuries, barotrauma, or decompression sickness, conditions that overlap with ongoing HBOT research and translational priorities.

Looking ahead, USF Health and TGH are evaluating opportunities for the development of a Hyperbaric & Undersea Medicine Fellowship Program, which would serve as Florida's first academic training pathway focused on hyperbaric science, safety, and clinical operations. If realized, this program would cultivate the next generation of physicians and researchers in hyperbaric and neurorestorative medicine, ensuring long-term workforce sustainability and advancing the state's leadership in this emerging field.

Should the HBOT Clinical Trial demonstrate positive outcomes, its findings could contribute to a future FDA submission to support HBOT as a therapeutic indication for mild-to-moderate TBI. Regardless of final outcomes, Florida's legislative investment has already catalyzed a durable infrastructure and knowledge base for the rapidly growing field of hyperbaric and neuro-restorative medicine. The HBOT Center and its partners are advancing a model that unites discovery, clinical delivery, and workforce deployment, ensuring that Florida remains at the forefront of veteran brain-health innovation and translational science for years to come.

## VI. OVERVIEW OF THE HBOT CLINICAL TRIAL – TBI AND PTSD

### **Purpose**

To evaluate whether HBOT improves symptoms and functional outcomes in veterans and active-duty service members with a history of mild-to-moderate TBI and PTSD. The study seeks to generate objective, reproducible data on the neurological, physiological, and psychological effects of HBOT using an FDA-regulated randomized-controlled framework. The clinical trial is conducted in accordance with 21 CFR Part 312 and Good Clinical Practice (GCP) standards, ensuring uniform regulatory oversight of all investigational treatments and data collection procedures.

## Specific Aims

1. *Aim 1: Evaluate Symptom Improvement*  
Determine whether HBOT produces measurable improvement in post-concussive and neurobehavioral symptoms compared to a placebo-controlled condition.
2. *Aim 2: Assess PTSD and Behavioral Outcomes*  
Examine changes in post-traumatic stress symptom severity, mood, and sleep quality associated with HBOT.
3. *Aim 3: Identify Physiological Correlates of Recovery*  
Integrate cognitive, imaging, and biological data to evaluate neural, inflammatory, and systemic recovery pathways influenced by HBOT exposure.
4. *Aim 4: Establish a Comprehensive Veteran Brain-Health Dataset*  
Establish a secure, de-identified repository of multimodal data to inform future DoD, VA, and NIH research priorities.

## Design

The HBOT Clinical Trial is a double-blind, placebo-controlled randomized controlled trial (RCT). A total of ~420 participants will be enrolled across four analysis cohorts (n = 105 each). Participants are randomized to receive either 40 sessions of HBOT or a placebo control over approximately 12 weeks.

Assessments are conducted at baseline, midpoint, and post-treatment to evaluate neurological, cognitive, and psychological outcomes. All procedures occur under USF Institutional Review Board (IRB) approval, with oversight by an independent Data Safety Monitoring Board (DSMB).

Data is securely coded and stored in compliance with FDA and institutional policies. The study's regulatory infrastructure ensures participant safety, data integrity, and adherence to federal research standards.

## Impact

- *Scientific Objective:* The study directly tests whether HBOT can safely and measurably improve symptoms of TBI and PTSD in veterans and active-duty service members.
- *Evidence-Based Evaluation:* By using a randomized, double-blind, placebo-controlled design under FDA oversight, the trial will provide the highest level of clinical evidence to assess HBOT's therapeutic potential and inform future standards of care.
- *Clinical Translation:* Findings will establish a scientific foundation for how HBOT may influence neurobehavioral symptoms, cognitive function, and overall quality of life following brain injury.

- *Broader Impact for Florida and the Nation:* Florida’s investment will produce results that help guide future research, clinical policy, and veteran rehabilitation strategies.

Neuropsychological assessment represents the core evaluative arm of the HBOT Clinical Trial, serving as the primary endpoint for determining whether hyperbaric oxygen therapy produces measurable improvements in cognitive, emotional, and behavioral function. These standardized, clinically validated assessments provide the benchmark against which all biological and imaging findings are interpreted, ensuring that the study’s outcomes reflect both scientific rigor and real-world relevance.

## 1. Neuropsychological Assessment – Cognitive and Emotional Function

### Purpose

To assess how HBOT influences cognitive performance, emotional regulation, and overall quality of life in veterans with TBI and PTSD. Neuropsychological testing provides a clinical anchor for interpreting the biological and neurological findings from EEG, imaging, and biomarker sub-studies.

### Specific Aims

1. *Aim 1: Evaluate Cognitive Domains*  
Assess attention, memory, processing speed, and executive function using standardized, validated instruments to determine change associated with HBOT participation.
2. *Aim 2: Measure Emotional and Behavioral Outcomes*  
Evaluates symptoms of post-traumatic stress, mood, and anxiety to quantify psychological improvements alongside physiological recovery.
3. *Aim 3: Correlate Clinical and Biological Measures*  
Integrate cognitive and symptom scores with EEG, imaging, and biomarker data to identify converging indicators of brain function recovery.
4. *Aim 4: Track Longitudinal Change and Durability*  
Monitor neurocognitive and behavioral outcomes across baseline, mid-treatment, and follow-up intervals to evaluate both immediate and sustained benefits of HBOT.

### Design

Participants complete standardized neuropsychological assessments under licensed clinical supervision at baseline and at defined post-treatment intervals. Instruments assess memory, attention, executive function, mood, and stress symptoms. All data are coded and stored in accordance with FDA IND and IRB requirements and integrated with biological sub-study outcomes to form a comprehensive picture of recovery.

## VII. RESEARCH AND TRANSLATIONAL SUB-STUDIES

### 1. Audiology – Blast Exposure, Auditory & Vestibular Function

#### Purpose

The translational framework of the HBOT Clinical Trial is designed to move beyond symptom measurement alone and uncover how recovery occurs across biological, neurological, and behavioral systems. By integrating multimodal datasets, the study seeks to identify objective signatures of brain repair that correspond with improvements in function and quality of life. This includes auditory function.

#### Specific Aims

- 1. Aim 1: Assess Baseline Outer Ear, Middle-Ear, and Hearing Function*  
Establish participants' auditory health at study entry to determine eligibility and generate baseline data for longitudinal comparison.
- 2. Aim 2: Monitor Auditory Function During Treatment*  
Conduct repeated otoscopy, tympanometry, and hearing assessments at multiple intervals to detect any pressure-related or therapeutic changes in outer, middle- and inner-ear.
- 3. Aim 3: Monitor Self-Reported Hearing & Tinnitus During Treatment*  
Conduct repeated self-reported assessments of hearing and tinnitus at multiple intervals to detect any pressure-related or therapeutic changes.
- 4. Aim 4: Evaluate Vestibular and Balance Responses*  
Screen for balance and dizziness-related changes associated with blast exposure and HBOT, incorporating participant-reported dizziness, vertigo, or equilibrium disturbances into longitudinal analysis.
- 5. Aim 5: Correlate Audiology Outcomes with Broader Study Measures*  
Integrate Findings with neuroimaging and neurocognitive data to explore associations between auditory function, neural connectivity, and symptom recovery.

#### Design

This sub-study follows standardized procedures. Assessments include:

- *Otoscopy*: Visual inspection of the ear canal and tympanic membrane.
- *Tympanometry*: Objective middle-ear analysis using the Titan Tympanometer. To measure ear canal volume, peak pressure, and compliance.
- *Teed Scale (0-5)*: Reporting using otoscopy and tympanometry to identify barotrauma, inflammation, or perforation of the tympanic membrane.

- *Self-Reporting Assessments:* Of hearing, balance, dizziness, and tinnitus using standardized measures.
- *Auditory Performance:* Thresholds measured via iPad-based *HearWho Digits-in-Noise* (DIN) test, assessing functional hearing in noise environments.
- *Follow-Up:* Repeat assessments conducted at pre-specified treatment intervals and at two weeks post-intervention to monitor changes over time

Results requiring medial referral are flagged by study protocol, and all assessments are performed by trained study staff.

## Impact

- *Integrated Validation:* Confirms whether HBOT-related symptom improvement corresponds with measurable changes in auditory or vestibular function.
- *Mechanistic Insight:* Clarifies how sensory and balance systems interact with neural recovery processes observed in EEG and fMRI sub-studies.
- *Safety Reinforcement:* Provides physiological monitoring that informs safe pressure exposure thresholds for participants with prior blast-related ear injury.
- *Cross-Study Correlation:* Enables linkage of auditory data with neuroimaging, EEG, and cognitive outcomes to explore multi-system recovery mechanisms.

## 2. Blood Assay Biomarkers – Inflammation & Regeneration

### Purpose

Purpose: To measure biological indicators of inflammation, neuronal injury, and cellular repair associated with HBOT. This sub-study examines biochemical pathways involved in neuro-repair and immune regulation to better understand the biological basis of observed clinical improvements in veterans with TBI and PTSD.

### Specific Aims

1. *Aim 1: Identify Neural Injury and Repair Markers*  
Track circulating biomarkers that reflect glial, axonal, and vascular integrity to determine how HBOT influences neural recovery mechanisms.
2. *Aim 2: Assess inflammatory and Immune Pathways*  
Examine systemic markers of inflammation and immune modulation to understand how HBOT affects whole-body healing and gut-brain communication.

### 3. *Aim 3: Evaluate Regenerative and Stem-Cell Pathways*

Explore biological signals associated with regeneration and neuroplasticity, advancing precision medicine approaches to veteran brain health.

### 4. *Aim 4: Correlate Biological and Clinical Outcomes*

Integrate blood biomarker data with imaging, neurocognitive, and behavioral outcomes to build a multi-dimensional model of recovery.

## Design

Blood specimens are collected longitudinally at key study time points and processed in collaboration with the Duke University Phase I Biomarker Laboratory. All biospecimens are coded, securely stored, and de-identified in the USF Health Biorepository.

Samples are analyzed for a panel of inflammation, neural injury, and repair-related biomarkers using validated assays. Long-term biobanking ensures that future investigations can expand upon these data to address evolving DoD and NIH priorities.

## Impact

- *Biological Correlation:* Establishes whether changes in symptom presentation align with quantifiable biological shifts in inflammation, vascular integrity, or repair markers.
- *Mechanistic Foundation:* Provides molecular context for the neurological and behavioral effects observed across imaging and cognitive measures.
- *Predictive Potential:* Supports identification of biological indicators that may forecast treatment response or long-term recovery patterns.
- *Integrative Validation:* Serves as a biochemical anchor that connects cellular-level repair mechanisms to clinical improvements measured throughout the HBOT trial.

## 3. EEG – Brain Activity & Neuroplasticity

### Purpose

To evaluate how HBOT affects brain activity, synchronization, and neuroplasticity in veterans with TBI and PTSD. Electroencephalography (EEG) provides a non-invasive, real-time method of brain function and recovery dynamics.

### Specific Aims

#### 1. *Aim 1: Measure Cortical Activation and Synchrony*

Quantify changes in brainwave activity and coherence to evaluate how HBOT intervention influences neural communication and cortical responsiveness.

2. *Aim 2: Assess Cognitive and Monitor Integration*

Examine patterns of brain activity associated with reaction time and cognitive performance, identifying markers of improved attention, processing speed, and executive function.

3. *Aim 3: Monitor Longitudinal Neural Adaptation*

Track changes across treatment milestones to assess whether neural patterns stabilize, strengthen, or reorganize following HBOT intervention.

4. *Aim 4: Correlate EEG Findings with Clinical Outcomes*

Link EEG-derived metrics with neuropsychological test performance and symptom scales to connect objective brain function changes to participant-reported recovery.

## Design

EEG recordings are collected longitudinally using a wireless, multi-channel headset system capable of capturing high-fidelity brainwave activity at rest and during task-based engagement including NeuroTask application that includes a battery neuropsychological assessments. Data are collected at baseline, midpoint, and post-treatment intervals to measure evolving neural connectivity and functional recovery.

All recordings are securely stored and de-identified for analysis. Analytical pipelines focus on spectral power, event-related potentials, and coherence to identify HBOT-related changes in brain synchronization and processing.

## Impact

- *Objective Neural Evidence:* Evaluates whether HBOT influences neural communication, synchronization, and functional efficacy corresponding to clinical gains.
- *Mechanistic Elucidation:* Contributes to understanding how HBOT facilitates network-level reorganization that may underlie cognitive and behavioral recovery.
- *Translational Utility:* Provides real-time, non-invasive evidence supporting the biological plausibility of HBOT's therapeutic effects.
- *Cross-Modal Integration:* Bridges electrophysiological findings with structural (fMRI) and molecular (biomarker) data to validate mechanisms of neuroplasticity.

## 4. fMRI -Structural and Functional Connectivity

### Purpose

To evaluate how HBOT alters brain structure and network activity in veterans with TBI and PTSD. Functional MRI (fMRI) captures changes in neural communication related to attention, memory, and emotional regulation, while diffusion tensor imaging (DTI) and volumetric analyses quantify neuroplastic repair.

## Specific Aims

1. *Aim 1: Map Structural Neuroplasticity*  
Examine white- and gray-matter structure to assess repair and recovery associated with HBOT.
2. *Aim 2: Quantify Volumetric and Morphometric Changes*  
Measure overall brain morphology using FDA-cleared volumetric software to identify patterns of restoration.
3. *Assess Functional Connectivity*  
Evaluate network communication efficiency and organization across key regions that govern cognition and emotion.
4. *Aim 4: Correlate Imaging and Clinical Outcomes*  
Link Imaging-based findings with neurocognitive and psychological assessments to demonstrate objective evidence of therapeutic benefit.

## Design

Imaging is conducted at the USF Health fMRI Research Core, using a GE 3.0T SIGNA Premier XT MRI system equipped with a 48-channel head coil.

- *Structural Imaging*
  - » High-resolution T1-weighted and diffusion sequences collected at Baseline B and 2-week post-treatment assessment. Additional sequences will include DTI (to capture FA values) pre and post treatment, as well as evaluation of perfusion imaging (ASL technique).
  - » NeuroQuant® v5.0 automates volumetric segmentation and cortical thickness measurements across 47 anatomical regions, generating FDA-cleared quantitative reports for longitudinal comparison.
- *Functional Imaging*
  - » QuickTome® Connectomics Suite (FDA 510(k) K222359) performs individualized connectome mapping using AI-based parcellation of 200+ brain regions.
  - » Outputs include graph-theory metrics (e.g., global efficiency, hub strength) and 3D network visualizations illustrating treatment-related functional reorganization
- *Integration & Data Security*
  - » DICOM data are transferred via secure cloud architecture (AWS HIPAA-compliant CTXclient Gateway) for offsite processing and encrypted return to USF Health servers.
  - » De-identified imaging data are stored in the fMRI Core's secure institutional repository and integrated with EEG, cognitive, and biomarker datasets under IRB and FDA IND oversight.

## Impact

- *Mechanistic Validation*: Tests on whether HBOT induces measurable structural or functional brain changes associated with cognitive and behavioral improvement.
- *Integration with EEG and Biomarkers*: Correlates imaging-derived evidence of neuroplasticity with electrophysiological and biochemical data to define converging recovery patterns.
- *Translational Application*: Establishes neuroimaging benchmarks that strengthen clinical interpretation of the trial's primary and secondary outcomes.
- *Framework Development*: Builds a reproducible imaging protocol to support ongoing and future HBOT mechanistic research.
- *Artificial intelligence (AI)*: Enhancing understanding of predictive outcomes in TBI and with HBOT therapy.

## 5. Medical Anthropology – Qualitative

### Purpose

To understand how veterans, their families, and the clinical team experience and interpret participation in the HBOT Clinical trial and how these perspectives influence engagement, recovery, and future access to care within Florida's veteran health ecosystem, with added emphasis on scientific and policymaker perspectives to complement these larger analyses.

### Specific Aims

1. *Aim 1: Capture Lived Experiences*  
Document veteran, caregiver, and research staff's real-life experiences to understand how cultural and social factors shape participation and perceived outcomes.
2. *Aim 2: Identify Barriers and Supports*  
Explore what helps or hinders access, engagement, and benefits from HBOT, including family support, logistics, and prior treatment perceptions.
3. *Aim 3: Understand Perceived Change*  
Learn how participants describe individual changes during and after treatment, and how those perceptions align with measurable outcomes.
4. *Aim 4: Examine Professional and Policy Perspectives*  
Capture how clinicians, staff, and policymakers view HBOT and other TBI treatments to inform evidence-based decision-making.

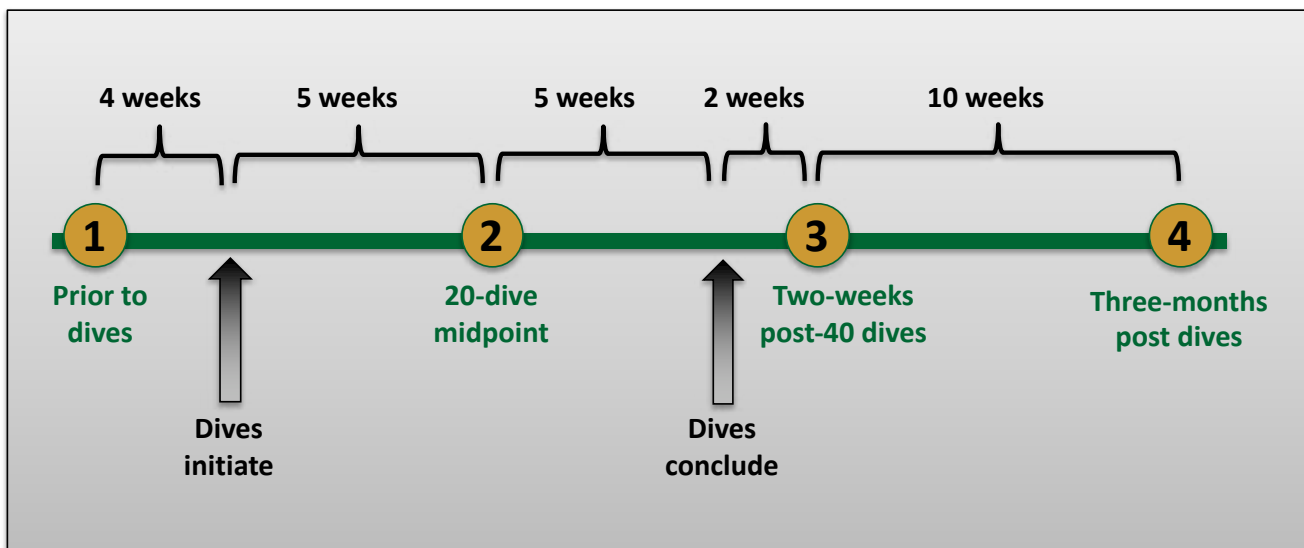
5. *Aim 5: Assess System-Level Factors*

Analyze broader policy, insurance, and structural issues affecting future implementation and sustainability of HBOT across Florida.

## Design

Semi-structured interviews with participants, caregivers, and study personnel at midpoint and 2-week post-treatment assessment, and 3-month post. Mixed qualitative and quantitative data are analyzed to identify behavioral patterns influencing participant engagement.

## Four Interview Data Collection Points, Participants and Care Partners



## Impact

Adds a human dimension to the clinical trial by illustrating how veterans and families experience HBOT, identifying real-world barriers to access, and informing future state and federal policies for veteran brain health and recovery programs. Utilizing a comprehensive framework involving six theories, from the micro (Theoretical Domains, Cultural Models, Ritualism), meso (Social Networks), and macro (Ecology of Care, Access to Care), the sub-study follows:

- *Behavioral Integration*: Contextualizes clinical and biological data with participant and family perspectives to explain engagement and recovery variability.
- *Human Factors Insight*: Identifies psychological elements influencing treatment adherence and perceived change, complementing quantitative outcomes.
- *Interpretive Correlation*: Enhances understanding of how subjective experiences align, or diverge, from measurable neurological and physiological recovery indicators.

## 6. Microbiome – Gut Brain Axis

### Purpose

To explore how HBOT may influence the gut microbiome and its relationship to systemic inflammation, cognitive performance, and overall recovery in veterans with TBI. This sub-study investigates the biological link between gut microbial communities and brain health to identify potential mechanisms of healing and resilience.

### Specific Aims

1. *Aim 1: Characterize Gut Microbial Composition*  
Examine overall diversity and relative abundance of gut microorganisms before and after HBOT to identify shifts associated with improved neurological or inflammatory outcomes.
2. *Aim 2: Assess Microbiome-Inflammation Interactions*  
Correlate microbial signatures with blood-based markers of inflammation and immune regulation to determine how HBOT affects systemic recovery pathways.
3. *Aim 3: Explore Functional and Metabolic Activity*  
Use metabolomic and genomic analyses to understand how HBOT may modulate microbial function related to neurotransmitter production, energy metabolism, and gut-barrier integrity.
4. *Aim 4: Integrate Microbiome Data with Clinical Outcomes*  
Link microbiome findings with neuroimaging, sleep, and neurocognitive measures to form a holistic understanding of the gut-brain axis in veteran rehabilitation.

### Design

Biological and behavioral data are collected longitudinally at key study time points, including baseline and post-treatment, under the parent FDA-regulated clinical trial protocol. All biospecimens are coded and de-identified for analysis at the USF Center for Microbiome Research, which performs sequencing and metabolic profiling using validated, IRB-approved methods. Dietary intake information is collected concurrently to contextualize microbiome shifts.

### Impact

- *Systemic Mechanistic Insight:* Explores how HBOT may affect the gut-brain axis linking microbial changes to inflammation and neurocognitive outcomes.
- *Cross-Domain Correlation:* Integrates microbiome data with biomarkers, imaging, and behavioral findings to understand whole-system recovery pathways.

- *Precision Medicine Potential:* Helps identify biological signatures that could explain individual variability in HBOT response and resilience.
- *Expanded Mechanistic Scope:* Extends the parent study's focus from neural repair to include systemic physiological adaptation to treatment.

## 7. Sleep - Oura Ring Wearable Health Technology

### Purpose

To assess whether HBOT influences sleep quality, circadian rhythm stability, and physiological recovery in veterans with TBI with or without diagnosis of PTSD. Continuous sleep monitoring through wearable health technology provides insights into how restorative processes may parallel any improvements in cognitive, emotional, and physical health during treatment.

### Specific Aims

1. *Aim 1: Evaluate Sleep Quality & Duration*  
Measure patterns of sleep onset, total sleep time, and nightly variability to assess how sleep metrics relate to clinical outcomes (e.g. cognitive scores and psychiatric symptoms) and biomarkers (e.g., blood and microbiome health).
2. *Correlate Sleep Metrics with System Improvement*  
Analyze relationships between changes in sleep quality and validated TBI and PTSD measures to understand if HBOT is associated with changes in sleep over time.
3. *Aim 3: Monitor Physiological Recovery Indicators*  
Track heart rate variability (HRV), resting heart rate, and body temperature as indicators of autonomic balance and determine if these are related to HBOT.
4. *Aim 4: Explore Feasibility of Wearable Health Technology*  
Assess the acceptability and feasibility of a long-term wearable device in a veteran sample.

### Design

Participants wear the Oura Ring Gen 4, a non-invasive, FDA-registered digital health device that continuously measures sleep and physiological patterns throughout participation (~15 weeks). Data are linked with other biological and clinical measures. The Oura Ring platform provides validated estimates of sleep quality, recovery indicators, and circadian trends across the course of HBOT exposure.

### Impact

- *Physiological Integration:* Determines whether changes in sleep quality and autonomic recovery align with neurobiological and behavioral outcomes.

- *Continuous Correlation:* Provides longitudinal physiological monitoring that complements imaging, biomarker, and neurocognitive data.
- *Mechanistic Clarity:* Enhances understanding of how restorative processes during sleep contribute to overall recovery trajectories in HBOT participants.
- *Innovative Methodology:* Demonstrates how wearable health technologies can enrich parent study by capturing dynamics beyond the clinic environment.
- *Quality of Life Impact:* Sleep is consistently identified as a key health indicator by our study population. Studying ways sleep may be improved through non-invasive wearable technology creates the opportunity to generate meaningful recommendations to our veterans and the medical and scientific community.

## VIII. OPERATIONAL GROWTH AND CONTINUOUS ENHANCEMENT

The HBOT Center continues process enhancement as operations scale statewide. Focused improvement initiatives in staffing, study integration, participant engagement, data management, and regulatory compliance ensure continued efficiency, safety, and long-term sustainability. These efforts reflect proactive management and the Center's commitment to operational excellence under Florida's state-funded mission.

### 1. Operational Expansion and Staffing

**Focus:** As participant enrollment continues to grow, the HBOT Center is preparing for a future dual-shift model to enhance scheduling flexibility and throughput.

**Action:** Cross training of clinical and research personnel is underway to ensure seamless transition once expansion aligns with staffing and facility readiness.

### 2. Sub-Study Activation and Integration

**Focus:** Specialized translational sub-studies, including Audiology/Vestibular and Medical Anthropology, are being activated.

**Action:** Coordination with IRB and sub-study teams to ensure efficient onboarding while preserving consistency with the main FDA-regulated trial.

### 3. Participant Engagement and Outreach

**Focus:** The Center continues to observe strong statewide interest among Florida veterans and is refining its outreach strategies to support informed participation.

**Action:** Strengthened partnerships with Veteran Service Organizations, local advocacy groups, and clinical collaborators to sustain engagement and awareness across Florida's veteran community.

#### 4. Data Integration and Quality Assurance

**Focus:** Integration of multimodal datasets remains a strategic enhancement but vital component of the trial’s translational framework.

**Action:** The USF Health Biostatistics Core is leading efforts to unify data pipelines, standardize analytic workflows, and ensure consistency across all research components.

#### 5. Regulatory and Process Optimization

**Focus:** As an FDA-regulated study, the HBOT trial adheres to rigorous documentation, reporting, and compliance standards.

**Action:** Updated standard operating procedures (SOPs), enhanced staff training, and digital process automation are streamlining compliance excellence and study coordination across multiple research units.

These improvement initiatives reflect the Center’s proactive management philosophy and its commitment to maintaining the highest standards of scientific integrity, participant care, and operational performance. The HBOT Center remains fully on track, continuing to advance Florida’s leadership in veteran-focused clinical research and translational innovation.

## IX. DISSEMINATION AND RECOGNITION

The HBOT Clinical Trial has garnered statewide and national attention as one of the most comprehensive and scientifically rigorous studies ever conducted on HBOT for TBI and PTSD. Through peer engagement, publications, and public education, USF Health is ensuring that Florida’s investment advances both the science of veteran brain health and the state’s reputation as a leader in translational medical innovation.

### 1. Peer and Scientific Presentations

Since its formal launch in December 2024, the HBOT Clinical Trial has been featured in several scientific and defense-medical forums highlighting Florida’s leadership in veteran-focused research.

- *Aerospace Medical Association (AsMA) – Undersea & Hyperbaric Medical Society (UHMS) 2025 Joint Annual Scientific Meeting:* Medical Director attended to remain current with global advancements in hyperbaric medicine, discuss emerging safety and regulatory strategies, and strengthen collaborations with national experts supporting future accreditation and commercialization planning.
- *Brain Injury Florida Conference 2025:* Featured participation in Florida’s statewide brain-injury conference to share lessons from study implementation, veteran engagement, and multidisciplinary rehabilitation collaboration.
- *USF Health Research Day 2025:* Researchers presented early translational and infrastructure work at USF’s largest university-wide research event, which drew over five hundred students, faculty, and researchers.

- *USF Health Office of Military Medical Innovation & Research (OMMIR) & Institute of Applied Engineering (IAE) Joint Roundtables:* Shared HBOT study methods and translational aims with the U.S. Special Operations Command (SOCOM) collaborators to align future federal funding opportunities and strengthen Florida’s position in defense medical innovation.
- *Special Air Warfare (SAW) Symposium:* Invited panelists speaking to Airforce leadership on military readiness for warriors in Ft. Walton Beach, Florida.
- *Home Base Veterans, Florida:* Invited panelist speaking to Veterans, legislators, and supporters of injured military about the state sponsored HBOT research study.

## 2. Publications and Academic Output

While the randomized controlled trial remains blinded, several non-interventional and methodological manuscripts are being developed to share early insights on infrastructure, safety, and translational integration.

- *ClinicalTrials.gov Registration:* Officially registered as NCT06581003 (December 2024), establishing transparency and national recognition of Florida’s funding research.

## 3. Community Outreach & Public Engagement

The HBOT Center embodies Florida’s commitment to serving its veteran population by extending impact beyond the laboratory.

- *Public and Media Recognition:* Local and statewide coverage has highlighted the HBOT Center’s role in advancing veteran brain health and the State’s leadership in translational medical innovation.
- *Legislative and Institutional Engagement:* The Center has hosted tours for Florida Legislators, university leadership, and veteran service organizations (e.g., Wounded Warrior Project, and Commissioner Cohen District I, a member of the Veterans Advisory Council of Tampa Bay) increasing awareness of its research, safety, and societal impact.

## X. COMMERCIALIZATION AND ACCREDITATION READINESS

The USF Health HBOT Center operates under rigorous research and safety standards that distinguish it as a world-class, FDA-regulated facility. As an IND study site, the HBOT Center upholds the highest level of institutional oversight to ensure participant safety, data integrity, and operational transparency.

As part of long-term sustainability planning, USF Health is developing a commercialization roadmap that will transition the Center from research-exclusive operations to a dual-use model supporting both clinical and translational applications.

A hyperbaric medicine consultant with national accreditation experience is set to advise the Center of documentation, safety policies, and infrastructure requirements for Undersea & Hyperbaric Medical Society (UHMS) accreditation once commercialization begins.

This phased approach ensures that Florida's legislative investment remains compliant throughout the study period. It simultaneously establishes the foundation for future clinical commercialization and accreditation. This framework will also support revenue generation, and statewide access to FDA-cleared HBOT indications.

## XI. LOOKING AHEAD – FY2026 PRIORITIES

FY2026 marks a pivotal year of transition for the USF Health HBOT Center, from establishing a successful single-shift clinical research operation to scaling statewide impact, expanding translational science, and formalizing long-term sustainability beyond the initial state appropriation.

Goals for the upcoming fiscal year:

- **Complete Cohort 1 and Launch Cohort 2**
  - » Complete data collection and treatment for all Cohort 1 (n = 105) participants, including post-treatment follow-up.
  - » Initiate Cohort 2 enrollment (target: 80+ new participants), expanding recruitment through communications and marketing initiatives, partnerships, social media, and word-of-mouth
  - » Continue maintaining zero-dropout and zero-safety-event standards under FDA IND #172640
- **Expand to Dual-Shift Clinical Operations**
  - » Implement a second daily shift to increase treatment capacity from ~24 to 48 dives per day.
  - » Recruit and train additional HBOT Technicians, APPs, and study coordinators under research compliance standards and study protocol.
  - » Validate the dual-shift model through operational readiness reviews and safety audits.
  - » Track impact on participant wait times and throughput for inclusion in FY2026 legislative reporting.
- **Advance towards Commercialization and UHMS Accreditation Readiness**
  - » Complete facility safety and compliance review and develop commercialization roadmap.
  - » Finalize documentation, staff credentialing, and medical oversight structure to prepare site for licensing.

- **Strengthen Translational Research Integration**

- » Compile and analyze integrated sub-study data in collaboration with the USF Health Biostatistics Core for Cohort 1.
- » Launch implementation of the Audiology/Vestibular sub-study and expand Medical Anthropology interviews.
- » Identify potential grant applications with NIH, DoD, and other funding agencies leveraging the HBOT datasets.
- » At the study's halfway point, evaluate the overall dataset and determine whether blinding continuation is necessary for the remainder of the trial to ensure scientific validity and regulatory compliance.

- **Enhance Veteran Workforce Development**

- » Sustain and expand the “Veterans Serving Veterans” employment model as often as possible, prioritizing veterans and military spouses as primary candidates whenever qualifications align with position requirements. While not all roles can be filled by veteran-affiliated personnel due to specialized research and clinical need, the Center remains committed to creating meaningful employment pathways for veterans within USF Health.
- » Work with the USF Institute of Applied Engineering and USF Office of Veteran Affairs to formalize partnerships with the DoD SkillBridge Program, enabling active-duty service members transitioning to civilian careers to gain hands-on experience in medical research, operations, and data management. This collaboration supports both workforce readiness and long-term institutional capacity building within USF's research enterprise.

- **Disseminate Findings and Increase Public Awareness**

- » Present early findings at national scientific meetings.
- » Publish at least two peer-reviewed manuscripts
- » Produce a FY2026 Mid-Year Impact Brief for the Florida Legislature summarizing recruitment, safety, and research progress.
- » Continue statewide outreach



## XII. CLOSING STATEMENT

The USF Health HBOT Center has successfully transformed the State of Florida's \$28 million investment into a nationally recognized research and clinical infrastructure advancing veteran brain health. In its first full year of operation, the Center achieved exemplary performance, demonstrating strong participant engagement, zero safety events, regulatory compliance, and seamless collaboration across academic, clinical, and industry partners.

What began as a legislative vision to serve Florida's veterans has evolved into a model of translational innovation, combining world-class research capability with a mission of public service. The HBOT Clinical Trial and its associated sub-studies are producing high-quality, federally competitive data that will guide the future of TBI and PTSD treatment. Beyond scientific discovery, the initiative has created new jobs, strengthened partnerships, and positioned the state as a leader in precision neurorehabilitation.

As the study advances into FY2026, the Center remains fully committed to upholding the State's trust through continued transparency, safety, and stewardship. With every participant enrolled, every dataset analyzed, and every veteran served, the Center honors Florida's investment by turning research into recovery, and evidence into impact.

## ▶ XII. APPENDIX

### 1. PERSONNEL



**Harry van Loveren, MD** is the David W Cahill Professor and Chairman for the Department of Neurosurgery, Brain, and Spine within the Morsani College of Medicine. He also serves as the Director of the USF Health & Tampa General Hospital Neuroscience Institute and Director of the USF Health HBOT Center. A board-certified neurosurgeon and nationally recognized academic leader, Dr. van Loveren, has served at USF Health for more than two decades, where he has overseen the expansion of one of Florida's most comprehensive neuroscience programs. Dr. van Loveren is widely regarded as a pioneer in skull-base and cerebrovascular surgery and has held leadership positions in several national professional societies, including the Congress of Neurological Surgeons and the North American Skull Base Society, where he previously served as President. His contributions to academic medicine include authoring seminal textbooks on skull-base surgery, mentoring generations of neurosurgeons, and advancing multidisciplinary collaborations between neurosurgery, neurology, and critical care. Dr. van Loveren's leadership has shaped statewide neuroscience collaborations and positioned USF Health as a national leader in translational brain health innovation, bridging academic medicine, hospital operations, and veteran-focused research.

As Principal Investigator and founding Director of the HBOT Center, Dr. van Loveren has led the development of Florida's first FDA-regulated, university-based hyperbaric research program focused on TBI and PTSD in veterans and active-duty service members. His proven ability to integrate clinical excellence, research innovation, and institutional leadership makes him uniquely suited to direct a large-scale, multidisciplinary translational study of this magnitude, one that unites discovery, clinical impact, and a lasting commitment to improving the lives of veterans and service members.



**Fayyadh Yusuf, PhD** is the Assistant Director for the USF Health HBOT Center and Assistant Professor in the Department of Neurosurgery, Brain, & Spine at the University of South Florida's Morsani College of Medicine. He earned his Ph.D in Leadership and Evaluation from the University of Virginia and has extensive experience in academic communication, program evaluation, and organizational development. Within the Center, Dr. Yusuf supports participant engagement strategy and communication alignment. He collaborates with key institutional and industry partners to coordinate messaging, data-sharing processes, and platform integration across the study's operational infrastructure.

Dr. Yusuf's academic foundation in leadership and evaluation provides a strong framework for his role in the Medical Anthropology sub-study, where he helps integrate communication analysis and participant-experience data into broader social-science evaluation. His commitment to fostering clarity, collaboration, and engagement across teams supports the HBOT Center's mission to conduct high-quality interdisciplinary research that advances veteran brain-health innovation and translational science.



**Mala Trivedi, MD** is the Medical Director for the USF Health HBOT Center and Assistant Director in the Department of Emergency Medicine at the University of South Florida's Morsani College. She is board-certified in Emergency Medicine and Undersea and Hyperbaric Medicine. She completed her residency in Emergency Medicine at New York Presbyterian Brooklyn Methodist Hospital in 2012, after which she worked as clinical faculty at academic emergency departments in New York for 5 years. In 2017, she pursued her fellowship in Undersea and Hyperbaric Medicine at the University of Pennsylvania, where she remained on as an Assistant Professor in both Emergency Medicine and Hyperbaric Medicine following her training. Dr. Trivedi integrates advanced clinical expertise with academic leadership to advance emergency and hyperbaric medicine. As Medical Director, she oversees the clinical staff, patient safety, and medical governance. Her vision extends beyond research to include academic program development, as she works to establish Florida's first Undersea & Hyperbaric Medicine Fellowship Program at USF Health, cultivating the next generation of clinicians and scientists in hyperbaric and neurorestorative medicine. Through her leadership in emergency medicine, hyperbaric operations, and medical education, Dr. Trivedi is advancing USF Health's mission to unify discovery, clinical delivery, and workforce development, ensuring that Florida remains at the forefront of veteran brain-health innovation and translational science for years to come.



**Rachel Karlnoski, PhD, CHRC** serves as the Executive Director of the Office of Clinical Research (OCR) at the University of South Florida, where she provides strategic and operational leadership for clinical research conducted across USF Health and Tampa General Hospital (TGH). She oversees institutional compliance with FDA, OHRP, and AAHRPP standards, ensuring the ethical conduct and regulatory integrity of all human subjects' research. Dr. Karlnoski leads the regulatory operations supporting the IND protocol and is responsible for maintaining compliance with FDA reporting requirements, including protocol amendments, safety reports, and annual submissions. A Certified Healthcare Research Compliance professional, Dr. Karlnoski has over 15 years of experience in clinical and translational research administration. She has directed the implementation of enterprise systems such as Velos CTMS and Florence eBinders, enhancing research transparency and efficiency. Her leadership reflects a deep commitment to advancing clinical research infrastructure, ensuring patient safety, and promoting high-quality, evidence-based care for veterans and the broader research community. Her leadership ensures that the HBOT Clinical Trial meets the highest standards of safety, regulatory compliance, and research integrity, protecting participants and strengthening institutional accountability.



**Victoria Sanchez, AuD, PhD** is the Division Chief of Audiology, and an Associate Professor in the Department of Otolaryngology Head & Neck Surgery at the University of South Florida's Morsani College of Medicine. She provides clinical services, teaches, and leads several research studies. She is a principal investigator in the Auditory Rehabilitation & Clinical Trials Laboratory (ARCT Lab), and her research areas of interest are speech perception, auditory cognitive neuroscience, auditory rehabilitation, evidence-based practice, and the effects of various disorders and interventions on the auditory and vestibular systems. Dr. Sanchez's current projects include developing and evaluating novel approaches to treat acquired forms of hearing loss and the treatment of auditory-vestibular systems.

Within the HBOT Clinical Trial, Dr. Sanchez serves as the Auditory and Vestibular Sub-Study Lead, overseeing pre- and post-treatment assessments of hearing, balance, and spatial orientation to

evaluate neurovestibular function following hyperbaric exposure. Her work integrates behavioral and physiological measures with neurocognitive outcomes, advancing understanding of sensory recovery and neural plasticity after TBI. Dr. Sanchez has authored more than 50 peer-reviewed publications and national presentations in auditory neuroscience and clinical rehabilitation.



**Alison Willing, PhD** is a Professor in the Department of Neurosurgery, Brain, & Spine at the University of South Florida's Morsani College of Medicine. Her research focuses on central nervous system injury and disease, conducting both pre-clinical and clinical studies aimed at developing novel therapeutic interventions. Her research program examines the therapeutic value of Brazilian Jiu Jitsu (BJJ) as a complementary treatment for PTSD in veterans, with current studies exploring gender differences in clinical efficacy and associated biomarker responses. Her preclinical studies investigate the role of inflammation as a major contributing factor to neuropathology of stroke and TBI, identifying inflammatory processes as key targets to neuroprotective and neurorestorative interventions, particularly cell-based therapies.

Dr. Willing serves as the Blood Biomarker Sub-Study Lead for the HBOT Clinical Trial, supporting the project through her expertise in neuroinflammation and neurorestorative mechanisms. She oversees translational analyses exploring cellular and inflammatory pathways involved in TBI recovery, advancing the understanding of biological responses to HBOT and contributing to the development of evidence-based, precision treatment strategies for veterans and service members. Dr. Willing has authored more than 100 peer-reviewed publications and book chapters on neuroinflammation and regenerative neuroscience.



**Nathan Schilaty, DC, PhD** is the Lincoln Endowed Chair of Chiropractic & Biomechanics Research and an Associate Professor in the Department of Neurosurgery, Brain, & Spine at the University of South Florida's Morsani College of Medicine, and the Department of Medical Engineering in the College of Engineering and USF Health. He received his Doctor of Chiropractic degree from Parker University in January 2007 and operated a private chiropractic practice for five years in Loveland, CO. While in private practice, he was an Instructor for Anatomy & Physiology at the local community college and continually curious about how chiropractic treatments worked at a neuromusculoskeletal level. Consequently, he enrolled in a graduate Neuroscience program and received his Ph.D in 2014.

He completed his postdoctoral research training at the Ohio State University and Mayo Clinic with emphasis in sports medicine, women's health, biomechanics, and motor control. While at Mayo Clinic, he became an Assistant Professor and his research included mentored training via T32, LRP, and K12 award mechanisms through the National Institutes of Health (NIH). He continues his innovative research of human motion and neuromotor control at the University of South Florida with funded research by NIH, the Department of Defense (DoD), industry, and foundations. His interests primarily focus on injury prevention and improved rehabilitation of concussion, neck, lower back, knee, and neurocognitive-related health conditions. Dr. Schilaty has published more than 70 peer-reviewed papers and remains a nationally recognized leader in biomechanics and neurophysiological research.

Within the HBOT Clinical Trial, Dr Schilaty serves as the EEG Sub-Study Lead, where he oversees neurophysiological data acquisition, processing, and interpretation to characterize neural recovery and cortical plasticity in veterans and service members undergoing HBOT. His work bridges biomechanics, neuroscience, and clinical practice to advance understanding of injury prevention, rehabilitation, and human performance optimization.



**Narayan Viswanadhan, MD** is a neuroradiologist and Chief of Radiology for the James A Haley Veterans' Hospital. He completed his Diagnostic Radiology residency at Albert Einstein Medical Center. He then went on to complete his Neuroradiology fellowship at the Brigham and Women's Hospital of Harvard Medical School where he also subsequently served as clinical faculty. He has published extensively in the field of Artificial Intelligence and Radiology and has spoken nationally related to this topic at Radiology Society of North America. He serves as an active member of the James A Haley AI committee and serves as subcommittee chairs of the Clinical AI Product and 3D printing committees. His clinical and research focus lies in deep learning and applications of AI in Neuroimaging. He is passionate about leveraging technology to benefit veteran care, and his unique experience across the academic, private and public sectors provides valuable insight into the emerging role of AI within healthcare.

Within the HBOT Clinical Trial, Dr. Viswanadhan serves as the fMRI Sub-Study Lead, overseeing advanced neuroimaging analysis to evaluate structural and functional brain changes associated with HBOT. His integration of AI-based image processing and radiomic modeling enhances precision in identifying neural correlations of recovery among veteran participants. Dr Viswanadhan has authored numerous peer-reviewed publications and serves on national committees related to clinical AI product development in radiology. His leadership ensure the integration of advanced imaging analytics and AI-driven approaches to enhance precision in neurorestorative research.



**Rebecca Campbell-Montalvo, PhD** is a medical anthropologist and Health Science Specialist at the North Florida / South Georgia Veterans' Healthcare System and a tenure-track Assistant Professor in the Department of Emergency Medicine at the University of South Florida's Morsani College of Medicine. She uses approaches grounded in social networks, cultural models, healthcare access, neuroplasticity, and neuroanthropology to do basic science to explain and predict health outcomes, as well as support the translation of insights into programming to effect change. She directs the Advancing Quality and Uniform Access through Social Sciences (AQUASS) Research Lab.

As the HBOT Medical Anthropology Sub-Study Lead for the HBOT Clinical Trial, she coordinates a team of experts to undertake the largest effort-to-date to employ social network mapping and related inquiry among TBI survivors and their care partners to understand the dynamic and complex social influences on clinical trial access and outcomes. Her VA research has included collaborative efforts to improve how people with TBI access care, especially through articulating policies to telehealth access among TBI survivors, the design of staff playbook to the TBI in-patient context, and the design of an electronic medical record flag to prompt providers to include caregivers for persons with TBI-related cognitive impairment.

Further, she leads qualitative investigation on several VA nephrology studies, working with colleagues to develop an evidence-based model and application to provide patient-centered care to Veterans with advanced chronic kidney disease to ultimately increase access to home dialysis. Previously, she supported evaluations on other projects, like The Substance Abuse and Mental Health Services' (SAMHSA) project REACH (Recovery, Engagement, Acceptance, Compassion, Hope), which investigated the effectiveness of interventions on opioid use and mental health. In addition, Dr. Campbell-Montalvo has published a monograph and held more than \$6M in National Science Foundation (NSF) funding as PI or Co-PI for work in educational anthropology. Prior to joining the University of South Florida in 2024, Dr. Campbell-Montalvo was at the University of Connecticut since 2016, where she served as Assistant Research Professor in her most recent role.



**Hariom Yadav, PhD** is the Director of the USF Health Center for Microbiome Research and a tenured Professor in the Department of Neurosurgery, Brain, & Spine at the University of South Florida's Morsani College of Medicine and a renowned leader in microbiome research with specialized focus in aging biology. Dr. Yadav has made significant strides in advancing our understanding of microbiomes' influence on aging and related disorders. His research emphasizes the use of microbiome modulators – such as probiotics, postbiotics, and dietary interventions, to improve health outcomes in aging populations. Dr. Yadav's work bridges microbiome science, aging, and neuroscience, leading several pioneering initiatives. He directs the USF Microbiomes Institute, which includes three core facilities devoted to microbiome research, and spearheads studies exploring the microbiome's role in aging among cancer survivors. His leadership in the Florida state-wide Microbiome in Aging Gut and Brain (MiaGB) consortium and the Metformin in Heart Failure with Preserved Ejection Fraction (MetPEF trial) and microbiome core in HeartShare projects highlight his innovative approach to understanding gut-brain and cardiovascular interactions in aging.

In addition to his academic endeavors, Dr. Yadav is co-founder of four startup companies, translating scientific discoveries into practical applications. His international recognition includes being elected a Fellow of Gerontological Society of America and a Senior Member of the National Academy of Inventors. With over 180 peer-reviewed publications, 17,340 citations, with an h-index of 59, his research is highly influential, particularly in the fields of microbiome and aging. Beyond his research, Dr. Yadav is dedicated to teaching and mentoring, having guided over 75 young scientists. His service extends to national and international committees, including the USF MCOM Appointment, Promotion, and Tenure Committee. Dr. Yadav has served as a keynote speaker and scientific advisor at numerous conferences, contributing significantly to global discussions on microbiome and aging. Through his interdisciplinary work, Dr. Yadav continues to drive innovative solutions for healthier aging, significantly impacting the scientific community.

Within the HBOT Clinical Trial, Dr. Yadav serves as the Microbiome Sub-Study Lead, directing analyses of gut-brain interactions and microbial signatures associated with neural recovery and psychological resilience following HBOT. His work links microbiome modulation with mechanisms of neuroplasticity and cognitive restoration in TBI and PTSD.



**Michael Schoenberg, PhD, ABPP-CN** is the Division Chief of the Division of Neuropsychology, and Professor in the Department of Neurosurgery, Brain, & Spine at the University of South Florida's Morsani College of Medicine. He is board-certified Clinical Neuropsychology and Pediatric Neuropsychology subspecialty and a licensed Psychologist with over two decades of experience advancing neurocognitive research and clinical practice. His research focuses on improving outcomes following neurosurgical intervention and better understanding recovery trajectories after concussion and TBI. Dr. Schoenberg has authored or co-authored more than 75 peer-reviewed publications and over 150 conference presentations at national and international levels. He serves as Associate Editor for Neuropsychology Review and co-editor of *The Little Black Book of Neuropsychology: A Syndrome-Based Approach*, now in its second edition.

Within the HBOT Clinical Trial, Dr. Schoenberg oversees the comprehensive neuropsychological evaluation of participants before and after hyperbaric treatment. His leadership ensures methodological rigor and consistency across the Center's neurocognitive testing arm, aligning clinical assessments with neuroimaging, biomarker, and behavioral data. Through his expertise in neuropsychology and data-driven interpretation, he plays a critical role in advancing the study's capacity to objectively evaluate therapeutic efficacy and long-term neurological outcomes in veteran populations.



**Shannon Miles, PhD** is a clinical psychologist at the James A Haley Veterans' Hospital and Associate Professor in the Department of Neurosurgery, Brain, & Spine at the University of South Florida's Morsani College of Medicine. Her research and clinical work focus on the interplay between mental and physical health after polytrauma (i.e., injury to more than one organ system). Clinically, she assists veterans and service members in their recovery after TBI, including the treatment of PTSD and aggression.

Within the HBOT Clinical Trial, Dr. Miles serves as the Sleep Sub-Study Lead, overseeing evaluation and analysis of sleep quality, circadian rhythm, and behavioral correlations of recovery before and after HBOT. Her leadership integrates psychological, physiological, and wearable-device data to examine how sleep restoration influences cognitive and emotional outcomes. Dr. Miles has co-authored numerous peer-reviewed publications on PTSD, sleep, and post-injury neurobehavioral recovery.



**Ambuj Kumar, MD, MPH** is a Professor of Medicine and Director of the Research Methodology & Biostatistics Core at the University of South Florida's Morsani College of Medicine. Dr. Kumar has over two decades of experience in evidence-based medicine, clinical epidemiology, and biostatistics, with a career dedicated to improving the methodological quality of health research and clinical practice guidelines. His work bridges clinical medicine and research methodology, with expertise in systematic reviews, meta-analysis, and clinical practice guideline development. His leadership has advanced numerous national and international collaborations, including with the American Society for Transplantation and Cellular Therapy, St Jude Global Health, and Cochrane Collaboration. A recipient of multiple awards for excellence in teaching and research – including the Thomas C Chalmers Award from the Cochrane Collaboration and the 2024 Distinguished Service Award from the American Society for Transplantation and Cellular Therapy – Dr. Kumar has published extensively in peer-reviewed journals and mentored countless medical students, residents, and fellows in evidence-based research practices. Through his research, mentorship, and global collaborations, Dr. Kumar continues to shape how evidence informs modern medical practice.

Within the HBOT Clinical Trial, Dr. Kumar serves as the Lead Data Analyst, overseeing study design, statistical integrity, and data analysis across all sub-study arms. His expertise ensures methodological rigor, consistency, and validity in evaluating the safety, efficacy, and translational outcomes of HBOT for veterans with TBI and PTSD.

## 2. VETERAN WORKFORCE SPOTLIGHT

The Veteran Workforce Spotlight highlights the distinguished service members and military-affiliated professionals whose leadership, discipline, and dedication from the foundation of the USF Health HBOT Center. Each team member brings a unique perspective shaped by military experience, translating those values of integrity, precision, and teamwork into a research mission dedicated to improving the health and recovery of veterans and active-duty service members.



Military Spouse

**Luis Estrada**

Clinical Research Associate

### Family Service Connection: Spouse

United States Air Force / National Guard

Senior Airman (Ret.)

Active Duty: 7 years

### Roles and Responsibilities

As a Clinical Research Associate for the HBOT Center, Mr. Estrada supports the coordination and implementation of daily clinical operations for veterans and active-duty service members participating in the Clinical Trial. He plays a key role in participant onboarding, scheduling, communication, and supports many of the sub-study arms (neuropsychological testing, EEG analysis, Oura Ring distribution). His work ensures seamless coordination between participants, study coordinators, and clinical teams supporting the accuracy, integrity, and human-centered delivery of research activities.

Luis's spouse served as a Senior Airman in the U.S. Air Force and Air National Guard, where they were responsible for the launch and recovery of fighter jets, ensuring operational readiness and flight safety. This close connection to the veteran community has deeply influenced Luis's commitment to veteran care and his dedication to advancing evidence-based research that supports their recovery and reintegration.

### What I Value Most

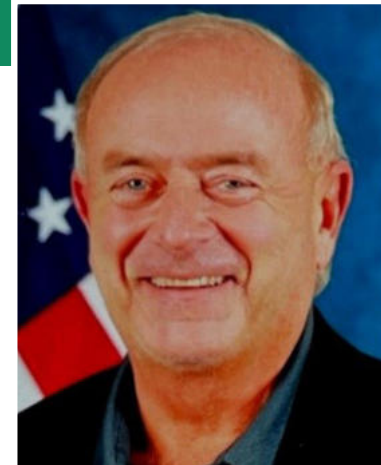
What I value most about working on this project is the opportunity to serve those who have served. My partner's experiences in the Air Force and National Guard, my father-in-law's time as a Marine, and the stories shared by veterans have shown me how profoundly service impacts lives. Supporting this clinical trial allows me to give back – to ensure our veterans and active-duty members receive the care and respect they have earned. Our military protects our nation; it's our duty to protect their health in return.

United States Air Force

**Colonel (Ret.) Les Folio, DO, MPH, ACHIP, CIIP**

Flight Surgeon & Deputy Commander of Aerospace Medicine

Active Duty: 20 years



### ► Roles

- Deputy Commander of Aerospace Medicine at Travis Air Force Base
- Lead Flight Surgeon
- Hyperbaric Oxygen Training Lead
- Telehealth Program Pioneer
- Combat Radiologist

### ► Roles and Responsibilities

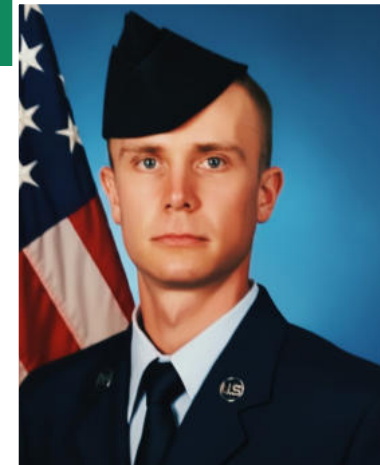
As a retired U.S. Air Force Colonel, Dr. Les Folio brings over two decades of leadership and innovation in aerospace medicine, radiology, and medical informatics. During his military career, he oversaw two of the largest hyperbaric oxygen chamber operations in the western United States and led the development of the Air Force's first telehealth program while stationed at the Pentagon. His operational experience spans deployments throughout the Middle East, including Iraq, Saudi Arabia, Qatar, and Yemen, and international assignments in Germany, Korea, and across the U.S. He has published over 160 peer-reviewed articles, five books, and pioneered "Combat Radiology", a coined term now referenced across military and academic medicine.

In his current role as Chief of Imaging Informatics at the James A. Haley Veteran's Hospital and Professor of the Departments of Oncologic Sciences and Radiology at the University of South Florida's Morsani College of Medicine, Dr. Folio supports the HBOT Clinical Trial through his expertise in imaging informatics and hyperbaric medicine, contributing to the advancement of evidence-based care for veterans with TBI and PTSD.

### ► What I Value Most

What I value most about this project is the opportunity to continue serving those who have served, applying lessons learned from the battlefield to the clinical and research environment. Having witnessed the impact of blast injuries firsthand, it's deeply meaningful to contribute to a mission that seeks not only to understand but to heal the invisible wounds of war. This work honors the dedication of our service members and reflects the same innovation and teamwork that defined my Air Force career.

United States Air Force  
**Senior Airman (E-4) Justin Helm, SD, CHS**  
Cryptologic Language Analyst  
Active Duty: 6 Years (2018-2024)



### ➤ Roles

- Cryptologic Language Analyst
- Counter-Narcotics and Counter-Terrorism Intelligence Specialist
- Liaison to the National Security Agency

### ➤ Roles and Responsibilities

Mr. Helm proudly served six years on active duty in the U.S. Air Force as a Cryptologic Language Analyst. After completing intensive training at the Defense Language Institute in Monterey, California, he became fluent in Spanish in addition to his native Portuguese and went on to serve with the National Security Agency (NSA) in Maryland. In this capacity, he contributed to critical counter-narcotics and counter-terrorism operations, protecting national interests and advancing global security. For his exceptional performance and service, Sr. Airman Helm was awarded the Joint Service Achievement Medal. His assignments required adaptability, cultural awareness, and precision – skills that have translated seamlessly into his post-military career in research coordination and patient engagement.

After his military service, Mr. Helm transitioned his focus toward health, safety, and research. He now serves as a Hyperbaric Safety Officer for the HBOT Center, where he supports compliance and daily participant treatments. His role ensures safety and efficient delivery of HBOT to veterans participating in the clinical trial, contributing to data integrity, participant safety, and operational excellence.

### ➤ What I Value Most

What I value most about this project is the opportunity to continue serving those who have served. Working alongside fellow veterans and medical professionals rekindles the same camaraderie, purpose, and dedication I experienced in the Air Force. It's deeply meaningful to play a part in research that not only advances science but also improves the lives of veterans and active-duty service members recovering from TBI.

United States Air Force

**Lt. Col. (Ret.) Susan Parda-Watters, DNP, MMOAS, MSN, APRN/ACNS-BC, CMSRN**

Chief Flight Nurse

Active Duty: 20 Years



### ► Roles

- Chief Flight Nurse
- Aeromedical Evacuation & Emergency Nursing Leader
- Adult Health Clinical Nurse Specialist
- Mentor & Veteran Advocate

### ► Roles and Responsibilities

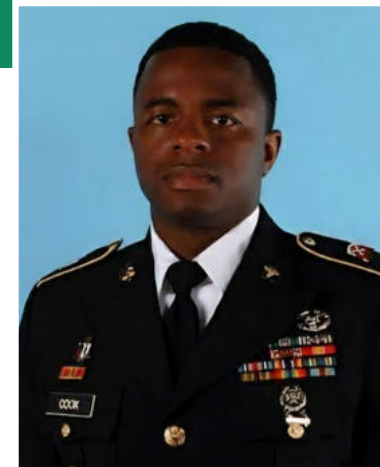
As a retired U.S. Air Force Lieutenant Colonel, Dr. Parda-Watters brings over two decades of distinguished service in aeronautical evacuation, flight nursing, and advanced practice leadership. Throughout her career, she served as Chief Flight Nurse and aeromedical operations leader, supporting critical-care transport and humanitarian missions worldwide. Her background in aerospace physiology and nursing systems guided initiatives to enhance patient safety and operational readiness across joint military environments. She holds doctoral and master's degrees in nursing practice and operational arts and sciences, uniting clinical expertise with strategic leadership.

In her role as an Advanced Practice Provider and Instructor I in the Department of Emergency Medicine at the University of South Florida's Morsani College of Medicine, Dr. Parda-Watters educates future nurse leaders and advances veteran-focused care through her service on the Hillsborough County Veterans Advisory Board. Her commitment to veteran health and community reintegration extends to mentorship within the 13th Judicial Circuit Veterans Treatment Court and outreach programs highlighted on the Frontline Nursing podcast, where she shared her experience bridging military nursing and civilian practice. Dr. Parda-Watters supports the HBOT Clinical Trial through her service as an Advanced Practice Provider conducting comprehensive patient assessments before and after hyperbaric therapy treatments to support safe, effective, and evidence-based care.

### ► What I Value Most

What I value most about this project is the opportunity to serve those who have served, applying decades of flight nursing, clinical leadership, and veteran advocacy to improve health outcomes for our nation's heroes. Participating in the HBOT Clinical Trial allows me to translate my military nursing experience into compassionate, evidence-based care that honors veterans' sacrifices and reflects the same dedication, teamwork, and integrity that defined my Air Force career.

United States Army  
**Sergeant First Class (Ret.) Jonathan Cook**  
Combat Medic & Allergy/Immunology Technician  
Active Duty: 20 years



### ► Roles

- Combat Medic
- Allergy and Immunology Technician
- Non-Commissioned Officer in Charge – Special Immunizations Program (USAMRIID)
- Small Group Instructor

### ► Roles and Responsibilities

As a retired United States Army Sergeant First Class, Jonathan Cook dedicated two decades to military medicine, infectious disease research, and soldier readiness. Serving as the Non-Commissioned Officer in Charge (NCOIC) of the Special Immunizations Program at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), Mr. Cook managed the administration of IND vaccines, ensuring safety, compliance, and protection for military personnel engaged in high-risk biomedical environments.

Throughout his distinguished career, Mr. Cook supported clinical and operational missions worldwide, combining medical expertise with a commitment to training and mentorship as a Small Group Instructor. His service strengthened the Army's ability to safeguard health and maintain operational capability in complex and challenging conditions.

Now part of the HBOT Center, Mr. Cook continues to advance that same mission through clinical research and HBOT supporting veterans and active-duty service members recovering from TBI and PTSD. His leadership, precision, and compassion enrich the study's culture of excellence and commitment to evidence-based care.

### ► What I Value Most

What I value most about this project is the opportunity to continue serving the veteran community through research that directly impacts their health and quality of life. My years in uniform taught me that readiness begins with well-being – and this project allows me to extend that principle beyond the military, ensuring that those who served receive the same level of care, protection, and respect they once gave to their country.

United States Navy  
**Commander (Ret.) Joseph Dituri, PhD**  
Engineering Duty Officer (Diver)  
Active Duty: 28 Years (1995 – 2013)



### ► Roles

- Special Operations Diver
- Engineering Duty Officer
- Chief Engineer / Program Manager – Undersea Systems
- Officer in Charge, Deep Submergence Unit Diving Systems Detachment

### ► Roles and Responsibilities

As a retired U.S. Navy Commander, Dr. Dituri brings nearly three decades of distinguished service in naval engineering, diving operations, and undersea systems development. Beginning his career as an enlisted sailor, he advanced through the Special Operations Diver pipeline before commissioning as an Engineering Duty Officer. During his military tenure, he led teams responsible for deep submergence system certification, saturation diving operations, and global submarine rescue initiatives. His leadership as Chief Engineer and Program Manager for Undersea Systems at U.S. Special Operations Command advanced the Navy's capabilities in maritime rescue and undersea safety technology.

Dr. Dituri holds a Ph.D. in Biomedical Engineering from the University of South Florida and M.S. in Astronautical Engineering from the Naval Postgraduate School. He currently serves as Associate Professor of Practice in the Department of Medical Engineering and Assistant Professor in the Department of Neurosurgery, Brain, and Spine at the University of South Florida's Morsani College of Medicine, where his research explores human performance and life-support design in extreme environments. As a TBI survivor, Dr. Dituri supports the HBOT Clinical Trial through his expertise in hyperbaric operations and protocol development, contributing to the advancement of evidence-based care for veterans with TBI and PTSD. His landmark "Project Neptune 100" (living 100 days in an undersea habitat) set a world record while advancing knowledge on the physiological and psychological effects of long-term hyperbaric exposure, informing applications in both space and undersea medicine.

### ► What I Value Most

What I value most about this mission is the opportunity to merge a career dedicated to diving, engineering, and service into scientific discovery that benefits those who protect and explore. The HBOT Clinical Trial unites my lifelong commitment to military medicine and my passion for understanding human adaptation under pressure. It is profoundly meaningful to contribute to research that supports veterans' recovery from TBI and advanced technologies that safeguard human life in the most extreme environments. As a TBI survivor, this work is deeply personal and gives an opportunity to translate my own recovery and operational experience into research that heals others and advances human performance under pressure.

United States Navy

**AT2 Kayla Steen SD, CHS**

Avionics Electronics Technician Petty Officer Second Class

Active Duty: 5 Years, 1 month (2017 – 2022)



### ➤ Roles

- Lead Calibration Technician
- Quality Assurance Representative
- Assistant Command Fitness Leader
- Training Representative

### ➤ Roles and Responsibilities

As the Safety Director for the USF HBOT Center, Ms. Steen oversees all aspects of safety operations, including compliance with NFPA 99 and UHMS standards, equipment maintenance, and technician training. In addition to her safety responsibilities, she also administers hyperbaric oxygen treatments to veteran participants, ensuring each session is conducted with precision, consistency, and adherence to research protocols. Her role supports the daily clinical operations that uphold both participant safety and research integrity within the ongoing TBI study.

### ➤ What I Value Most

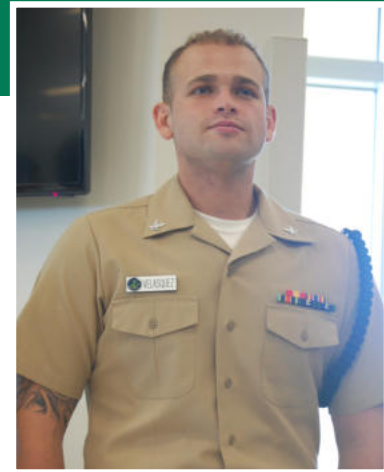
What I value most about this role is the opportunity to reconnect with fellow service members and contribute to a mission that continues beyond uniformed service. I enjoy the familiar sense of camaraderie, sharing stories, humor, and respect among veterans and seeing how their participation shapes the future of TBI research. It's deeply meaningful to help ensure they know their time and experiences remain valued, and that their contributions continue to make a difference long after active duty.

United States Navy

**AT2 Erik Velasquez**

Avionics Electronics Technician Petty Officer Second Class

Active Duty: 6 years, 11 months (2011 - 2018)



### ► Roles

- Avionics Electronics Technician
- Calibration and Maintenance Specialist
- Quality Assurance Inspector
- Command Training Representative

### ► Roles and Responsibilities

As a U.S. Navy Electronics Technician Petty Officer Second Class, Mr. Velasquez served more than 6 years in naval aviation operations, supporting mission-critical aircraft readiness and flight safety maintenance on advanced avionics systems used in airborne operations worldwide. His role required strict adherence to technical manuals, aviation safety standards, and team-based coordination to ensure operational excellence and mission continuity under pressure.

After honorable service, Mr. Velasquez transitioned his technical discipline and attention to detail into clinical research operations. He now serves as a Senior Clinical Research Associate in the Office of Clinical Research at the University of South Florida's Morsani College of Medicine. He is the Manager of the Clinical Research Study Coordinators on the project, where he supports the HBOT Clinical Trial through protocol adherence, data quality assurance, and regulatory coordination. His Navy background in systems analysis and operational safety continues to inform his approach to precision, compliance, and mission focus in veteran-centered research.

### ► What I Value Most

What I value most about this mission is the opportunity to carry forward the values instilled in me by my Navy service (discipline, teamwork, and purpose) into a field that directly impacts the lives of veterans and service members. Supporting the HBOT Clinical Trial allows me to contribute to research that advances healing and optimizes human performance while remaining connected to mission-driven community that reflects the same dedication and integrity that defined my military career.

Royal Navy

**Sub-Lieutenant (Ret.) Andrew Spencer, RN, SD, CHSS**

Medical Assistant & Training Officer

Active Duty: 26 Years (1987 - 2013)

### ► Roles

- Royal Navy Medical Assistant
- Full-Time Reserve Medical Support Officer
- Training Officer – University Royal Naval Unit (Glasgow & Strathclyde)

### ► Roles and Responsibilities

As a retired Royal Navy Sub-Lieutenant, Mr. Spencer dedicated more than two decades to operational medicine, leadership development, and officer training. Beginning his naval career in 1987 as a Royal Naval Medical Assistant, he delivered emergency and primary care aboard deployed surface vessels and shore establishments, managed medical logistics, and instructed junior crew in first aid and hygiene procedures essential to fleet readiness.

Following active service, he continued full-time in the Royal Naval Reserve, providing medical support for diving and maritime operations, coordinating multi-service exercises, and teaching applied medical response within his units. In 2003, he received his commission as a Royal Navy Training Officer with the University Royal Naval Unit (Glasgow & Strathclyde), where he designed and delivered blended instruction on naval theory, leadership, communications, and medical readiness. His mentorship helped many midshipmen and junior officers transition into full-time Royal Navy careers while fostering professionalism, resilience, and ethical leadership across his command.

After retiring from service, Mr. Spencer continued his commitment to public safety and veteran care as an Emergency Medical Technician and now serves as a Hyperbaric Safety Officer for the HBOT Center.

### ► What I Value Most

What I value most about this project is the opportunity to continue serving those who have served. Working alongside fellow veterans and medical professionals allows me to merge decades of operational excellence with a mission that directly benefits our veteran community. It's deeply rewarding to help ensure the safety, comfort, and confidence of veterans participating in this transformative research.

Military Spouse  
**Erica Campbell**  
Clinical Research Associate



► **Family Service Connection: Spouse**

- United States Army
- Sergeant First Class (Ret.)
- Active Duty: 10 years

► **Roles and Responsibilities**

As a Clinical Research Associate for the HBOT Center, Mrs. Campbell plays an essential role in participant recruitment, engagement, and tracking through the Ripple Platform, supporting the study's overall recruitment strategy and operational efficiency. She works closely with research coordinators and leadership to streamline veteran and active-duty participant management, ensuring effective communication, scheduling, and data integrity across all sub-studies. Her expertise with Ripple facilitates transparent workflow management, enhances participant experience, and strengthens the Center's ability to meet recruitment milestones and compliance standards for the clinical trial.

Her spouse served as a Sergeant First Class in the United States Army, where he was a Combat Engineer, responsible for ensuring mobility for friendly forces and denying mobility to the enemy. Her connection to the military community is deeply personal – her grandfather served in the Army, her father in the Marines, and her two sons currently serve in the Air Force, continuing a proud family legacy of military service.

► **What I Value Most**

What I value most about working on this project is that it allows me to serve those who have given so much to our country. With generations of my family having served, this mission is personal. Supporting the HBOT Clinical Trial gives me the opportunity to give back in a meaningful way - helping improve health, recovery, and quality of life for veterans and active-duty service members.

### 3. ORGANIZATIONAL CHART OF PERSONNEL & SCIENTIFIC CONTRIBUTORS

The following pages present two participant profiles along with an organizational chart detailing program leadership and key personnel.



## “ETHAN”, 44-YEAR-OLD MARINE VETERAN

Ethan has lived with effects of multiple TBIs from mortar blasts, improvised explosive devices, and service accidents—though he “didn't get directly blown up.” A couple years ago he sustained a TBI from being rear-ended at full speed.

### CASE SUMMARY

Ethan completed 32 dives, and has not yet been unblinded. He was optimistic about the HBOT study—mostly for its potential to ease his symptoms; he hoped it would help make HBOT more available, a treatment many Veterans endorsed to him. He remained comfortable, citing the Center's clean appearance, technology, and staff competence, though traffic and gowns were a drawback. Mindfulness and entertainment helped him pass chamber time. The study's purposeful Veteran-based design was seen in his feedback. Ethan reported no major effects.

### DATA

Ethan completed two interviews and two observations. Interview 1 occurred pre-dives, and Interview 2 midway (post-Dive 14). Observations were at Dive 1 and around midpoint (Dive 18).

- Interview 1 (Pre-Dives)
- Observation 1 (Dive 1)
- Interview 2 (Dives Midpoint)
- Observation 2 (Dives Midpoint)
- Observation 3 (Coining)
- Observation 4 (Reveal, 2 weeks post-dives)
- Interview 3 (Post-reveal)
- Interview 4 (3 months post-dives)

### IMPORTANCE OF HBOT STUDY PARTICIPATION TO ETHAN

Ethan participated mostly *for his own symptom improvement*, but he also realized that the study might *help make HBOT more available*.

- In Interview 1, Ethan said he participated “because of just some of the challenges that I’ve had since my multiple TBI and concussions ... if I can get a benefit of healing out of it ... If I can improve some more, if there’s room for improvement, let’s do it ... We’ve kind of slowed down with trying to figure out what helps Veterans heal from some of these injuries. I almost feel like it’s not as exciting as it used to be because we’re not in all these wars.” He added that he heard of the study from USF Health, where he used to be a student and employee.
- He echoed in Interview 2, “If there’s room to get even more better and get part of my life back [with HBOT], it’s well worth it ... I’m invested in my life and my health, because there was a time not too long ago where I felt like, man, I think my body’s just—it’s about to crumble and I don’t know how much time I have ... This is a lot less invasive, with ... a return on health.”
- He also mentioned in Interview 2 how his participation in this study might help increase the availability of HBOT therapy, “I hope that if the data comes to fruition and the juice is worth the squeeze, I hope the VA enables that across the country.”

Ethan's *preexisting symptoms* were numerous, and classic of TBI.

- In Interview 1, he recalled, “My cognitive [function] had been going down while I was still on active duty ... I was diagnosed with TBI on my transition out of the Marine Corps ... My biggest issues are brain fog and I had a really bad stuttering ..., balance issue ..., vision issues ..., another TBI associated issue I have was migraines ... [In terms of my social contact with others,] I am not the best communicator all the time or staying on top of things. Either I forget ... So [when it comes to my social participation, there’s] room for improvement.”
- In Interview 2, he echoed, “My vision ..., speech, cognitive ,and memory issues ... staying on schedule, remembering things correctly. I still do word searching a lot of times when I’m having a conversation ... a little bit of a stutter. ... I was pretty bad with my balance ... Then migraines were really bad, light sensitivity. Anger management .... I might just take [something] the wrong way and go 0 to 60 in a flash of a second ... very frustrating ... Exhaustion from using my brain, ... if I have to make decisions. Something as simple as what clothes to wear ... [At] the grocery store ... I start stressing out because I’m having a hard time making decisions ... Halfway through the day I’m going to have to nap ... [Sleep is one of] my biggest challenges.”

For Ethan, *some standard TBI treatments, like cognitive therapy and medication, were effective*, though *barriers he faced accessing treatment made him discontinue* some.

- In Interview 1, Ethan named therapies he tried: “Speech ... cognitive training ... vestibular therapy ... vision therapy ... migraine medication ... supplements ... [I’m not into] drugs.”
- In Interview 1, he talked about their effectiveness: “[Cognitive therapies were] very effective ... negated migraines down to 0-2 a month ... The vision therapy I never really completed because of COVID ... they only had one provider at the time ... Sometimes they had a shortage of personnel in vestibular, I’d have a challenge getting in ... last time, I did it out in town on my own using Tricare ... Got some improvement in some areas, some stuff the same.”
- Also in Interview 1, he described trying HBOT in the past, “They’re recommending ... hyperbaric chamber ... I did not do it routinely. I’d do it two weeks here, two weeks there and then I’d go for a whole gap of a month ... I just didn’t really do it on a set period.”

He had also received *much input from others, including many Veterans, which endorsed HBOT*.

- In Interview 1, he recalled, “I’ve just on occasion talked to a Veteran, and that’s how I learned about the benefits of hyperbaric chamber ... folks over at Semper Fi Fund or folks at VA. I’ve heard of a couple guys going to Miami where they do treatment for the bends, and then a couple guys in South Texas and San Diego. Generally, almost everyone I’ve heard of doing this sounds like they all got some great benefit ... a lot of their brain healing, helping them with their brain fog ... If that’s really happening, my eyes have definitely opened up to trying new things ... I do have a good friend of mine that’s been through it and he said it’s helped him a lot ... Honestly, I haven’t heard anything negative about it.”

## ETHAN'S STUDY EXPERIENCE

Ethan was *comfortable with the study, team, and Center*—he did remark on traffic making study participation more difficult, and desired more modest gowns.

- In Interview 1, Ethan shared how the Center helped him feel comfortable, “**I was a little nervous at first and now I’m chomping at the bit because I’m really looking forward to going through it ... [The other place I received HBOT is] not on the same clinical level.**”
- In Interview 2, he elucidated on his Center perceptions, “I think it was extremely clean and professional and it had a welcoming presentation ... If there is something to be experienced or seen or healed, this will be it, not what I’ve been [receiving before] ... I wouldn’t even look twice at the first place I went to for HBOT because this seems much more legitimate.”
- In Interview 2, he explained how the study was being run: “Other than not knowing whether I have placebo or not, it’s going very smooth, very easy ... I’m not spending all day there and [it’s] pretty easy structured routine ... The process to everything is very legitimate ... I go in every single time with an open mind hoping that I’m getting the medicine and, if not, I know I’ve been offered to come back and [receive treatment] ... It’s a clinical study.”
- In Interview 2, Ethan shared positive views of personnel, “I love them all. They’re all awesome ... [One was] either RAF or Royal Navy ... [The other], he’s an Air Force cat ... Primarily, I’ve worked with [the research associate] ... a Navy Vet. He runs the program, he’s great ... The nurse practitioner and the PA, they’re great and extremely professional ... I don’t have one negative thing to say about any staff ... The people will definitely make it easier.”
- Interview 2 Ethan was “absolutely” comfortable in the study, rating his comfort a 9 out of 10: “Because I’m in a gown, there’s still a little bit of vulnerability ... You cannot wear undergarments ... You got ... one lady tech over there and she’s primarily working with me every time. Sometimes I’m waiting for her to look the other way so I can get out of the rack, because every single time I feel like I’m doing a ... what’s that movie with Sharon Stone?<sup>1</sup> ... I wish [the gown] was a little longer or they had pants ... My only complaint.” (Fig. 4)

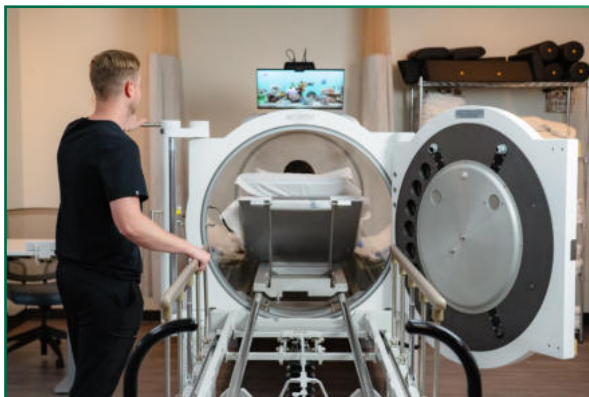


Fig. 4 View of chamber, ‘rack’

<sup>1</sup> In *Basic Instinct*, Sharon Stone’s character crosses her legs, and a revealing angle is used.

- Another drawback in Interview 2 was the drive, “I dread my drive every day ... the hardest part to me is probably just the drive and the traffic.”

Ethan’s dives entailed *routine, entertainment and mindfulness, and Veteran-centric atmosphere*.

- In Interview 2, Ethan described diving, “I’ve developed a little bit of a routine. I come in there ... I’ll use the restroom and go to my locker [to store belongings] ... [I’ll] go back to the changing room ... fill up my water bottle ... They pull out the rack and I lay down. They take my vitals ... We’ll talk about whether someone’s going on vacation or ... shows or we’re talking food.”
- In Observation 2, Ethan’s dive was unremarkable. He was awake, with his hands folded behind his head watching *The Terminal List*. Two technicians monitored and informed him of the descent and ascent processes. Throughout, Ethan occasionally shifted arm position but remained otherwise still. Midway through a technician checked on him again, and a few minutes later they communicated by chamber phone to change the channel. During the ascent Ethan turned his head to the side, closed his eyes, and covered with a blanket.
- For entertainment, in Observation 2, prior to the dive, a technician asked what he wanted to watch, and Ethan joked that he was his “TV Guide,” referencing the magazine. They held an extended conversation about television, movies, and shared schooling experiences.
- In Interview 2, Ethan detailed how he dealt with the dive process, “[To manage a dive, there’s] TV, they have different apps: Disney, Prime, and Netflix, ... YouTube ... My breathing exercises, so I do that for about 6 minutes’ worth and then I’ll just do some stretching and pay attention if I’m starting to get a little cotton mouth, I’ll just sip on the water.”
- In terms of the Veteran-centric environment, in Observation 1, two medical staff greeted him upon his arrival. The conversation turned to service, and a medical staff shared her experience in the Air Force. Ethan responded by sharing his and his mother’s military experiences.
- In Interview 2, he described the team, **“All the techs are awesome. The fact that there’s that Veteran component to it, definitely I can relate and have conversations with everyone ... Even your civilian staff’s pretty awesome ... All the Vets over there, we can speak on the same level. It would probably take me longer to get comfortable with a civilian and I always got to watch what I’m saying around civilians ... [With Vets,] we can joke ... from boot camp to dining facilities to living quarters ... We can all relate. It does make it a lot easier. It helps with that.”**
- In Observation 2, first, Ethan held a long, pleasant conversation with a medical staff about scheduling the next assessment appointment. The conversation evidenced a healthy rapport and the speakers stood close together. Then, Ethan and a technician laughed together about eating cheap ramen noodles, and another technician showed him something on his phone. At the end, Ethan smiled and joked with the medical staff about scheduling, mixing up Wednesday with Monday, grinning that his wife calls that his “TBI brain.”

## REFLECTIONS ON HOW ETHAN WAS AFFECTED BY STUDY PARTICIPATION

Ethan had no major impacts.

- In Interview 1, Ethan discussed how the study might affect him, “[On a scale from 1-7, I expect the treatment to affect me at a] 3.5, so 4 ... safely say a 5 [moderately better with some slight but noticeable changes] ... I’m being optimistic ... even if it’s not too major.”
- Also in Interview 1, Ethan talked about whether he thought there might be any risks, “[In terms of risks, am I expecting [them]? No. But there’s always risks to doing anything, right? So.”
- In Interview 2, Ethan reported aches, “The first day when I had the body aches, I didn’t think much of it. But then when it lasted about a day ... or two and a half days. That’s when I noticed and ... put ... the bolster under my knees and it went away and I didn’t think twice about it.”
- In Interview 2, he talked revisited expectations, “I didn’t have any exact expectations to begin with ... What exceeded my expectations is I didn’t know it was going to be so easy to do.”
- In Interview 2, he described study effects, “I don’t know if I’m feeling anything just yet. I think I am because I’ve been doing clean eating ... breath exercises. Maybe I’m losing weight ... I don’t know if [treatment is] helping ... If there’s changes, I don’t feel like it’s extreme.”



## “JAMES”, 61-YEAR-OLD US ARMY VETERAN

James sustained a symptomatic mild TBI after being “blown up” in an Iraqi combat zone in November 2006 when a roadside bomb detonated on the driver’s side of the Humvee he was operating.

### CASE SUMMARY

James completed 40 dives and has not yet been unblinded to learn whether he received treatment or placebo. He found the HBOT study personally meaningful—both for its potential to ease his treatment-resistant symptoms and to help other Veterans. He remained comfortable throughout, citing the team’s competence, entertainment, clear communication, and monitoring as key to his positive experience. The study’s cultural alignment with Veterans was evident in his feedback. Though his treatment grouping is unknown, James reported symptom relief and fulfillment from participation.

### DATA AND METHODS

James completed two interviews and three observations. Interview 1 was pre-dives and Interview 2 was at midpoint (post-Dive 18). Observations were at Dive 1, midway (Dive 22), and coining (Dive 40). All data were analyzed using reflexive thematic analysis<sup>1</sup>, excluding social network items (forthcoming).

- Interview 1 (Pre-Dives)
- Observation 1 (Dive 1)
- Interview 2 (Dives Midpoint)
- Observation 2 (Dives Midpoint)
- Observation 3 (Coining)
- Observation 4 (Reveal, 2 weeks post-dives)
- Interview 3 (Post-reveal)
- Interview 4 (3 months post-dives)

### IMPORTANCE OF HBOT STUDY PARTICIPATION TO JAMES

James participated in the study *for his own symptom improvement and to help Veterans.*

- During Interview 1 he explained, “**Because I have a TBI, I want to see if I can get some kind of fixing of it, and maybe if I can help another Vet, that’s a great thing ... I just want to try to get better. If I can help myself and help my family, help other Vets, I’m all about it because we the Vets get pushed aside too often.**”
- Interview 2 echoed, “Anything I can do to help myself and other fellow Vets, I’ll do it. **If it helps somebody, helps save one life, it’s worth it ...** We, the Vets, don’t get looked out for enough.”
- The Coining Observation reiterated, James planned to place the challenge coin<sup>2</sup> alongside honors received after being “blown up.” He said, “This coin means I’m going to help another Vet” (Fig. 1).



Fig 1. The HBOT Study Challenge Coin

<sup>1</sup> Braun, et al. (2023). Doing reflexive thematic analysis. In *Supporting research in counselling and psychotherapy: Qualitative, quantitative, and mixed methods research*. Cham: Springer International.

<sup>2</sup> Wounded Warrior Project notes, “Challenge coins are small medallions that represent an achievement, membership, or affiliation to a specific group ... they often symbolize a special event or mission, anniversary, meeting with a leader ... challenge coins have been an American tradition for a century.”

James' *preexisting symptoms* included classic signs of TBI along with service-related effects.

- In Interview 1, James described his symptoms, “I get real aggravated. I get tired, I get snappy. I lose all the interest and everything and can’t stay focused ... I take a lot of notes nowadays, ... otherwise I forget things ... I’m a construction estimator ... [and] do a lot of computer work, so I do a lot of eyeball straining, which gives me a headache.” His symptoms intersected with service-related social impacts, “When I first got out of the military, ... I [was “skittish,”] I couldn’t get on an airplane ... The fear of, I don’t know these people, so I don’t know what they’re going to do.” These impacts caused “mild difficulty in social situations” for him.

For James, *standard TBI treatment was ineffective*, so he stopped seeking it.

- In Interview 1, James described having tried counseling to treat his TBI, “I retired in 2008. The VA had given me some counseling for it.” When asked whether it was effective, he said, “No, not really.” He explained how counseling provided him compensatory strategies to help with memory, like notetaking, adding, “I take notes anyway in my job, I have to.” Until he heard about the HBOT study from a letter sent by the VA, he was resigned to deal with his symptoms; he said, “I don’t do much [to try to treat my TBI] anymore. I just kind of live with this thing.”

### JAMES’ STUDY EXPERIENCE.

James was *comfortable with the study, team, and Center* (Fig. 2).

- During Dive 1 Observation, James arrived early, with neutral expression. He greeted others and chatted with a medical staff member about participant arrivals. A technician explained the procedure and banned chamber items, prompting James to erupt with laughter that “wigs and nails” were not allowed. As he signed the consent, he mentioned his scuba experience might help with pressure adaptation. Across the clinic, staff celebrated another participant’s 40th dive, and James smiled before changing into his gown. Next, he settled on the gurney as a technician described the technology. Afterward, he dapped<sup>3</sup> a medical staff member, smiled, and headed toward the exit.
- During Interview 2, when asked to rate on a scale of 1-10 his comfort participating in the study thus far, James responded, “15 ... the whole experience has been great. The people, the process, what it’s doing for me personally, it’s all been absolutely amazing.”



Fig 2. Non-study participant in lobby

<sup>3</sup> Emerging during the Vietnam war among Service Members, a dap is a type of handshake characterized by a partial hug. See LaMont Hamilton's Smithsonian *Folklife Magazine* 2014 article for more, “Five on the Black Hand Side: Origins and Evolutions of the Dap.”

- In Interview 2, he described positive interactions and reliability of the team, “[The technicians], they are all super great. They make you very relaxed when you’re in there. They make the whole process so much easier ... [The medical staff member,] she’s super ... Everything that I’ve done with the hyperbaric oxygen staff has been amazing ... All [the technicians] that run the actual machines and then the [medical staff], they’re all great people. They all have a sense of humor ... **All the other study staff has been very helpful, very professional. They’re on top of everything that they’re doing. I’ve had no issues.**”
- In Interview 2, James described his first impression of the Center, “It was an amazing thing to see it originally ... **Everything is super pristine and clean and in order, not chaotic. ... Heck yeah [I felt welcome there] ... They went out of their way to make me feel welcome.**”
- At the Midpoint Observation, James again was a little early for his appointment.
- At the Coining Observation, scheduling for the two-week follow-up appointment was discussed. James responded affirmatively, saying, “I haven’t missed an appointment yet.” As he waved goodbye, a medical staff referenced his usual early arrivals, joking, “Don’t be late!”

James’ dives were *hallmarked by pressure, supported by entertainment, continuously informed, and medically-monitored by competent and a personable staff* comprised of mostly Veterans.

- At Dive 1 Observation, James opened and closed his mouth often, experiencing diving reflex<sup>4</sup>.
- In Interview 2, he described the sensation, “Feels like I’m going 30 feet underwater ... You have to clear your ears, just like when you fly. [The pressure], it’s there. But you don’t really feel it, ‘cause once you clear your ears, you balance yourself out.
- At Dive 1 Observation, James conversed with the technician, who then turned the TV on to James’ preferred movie (Fig. 3).
- In Interview 2, James linked entertainment to comfort, “I watch Netflix, I watched the whole series of Frontier and I’ve seen a couple movies ... sometimes I get so relaxed I fall asleep ... That’s my one hour of nobody calling me ... bothering me at work ... to decompress ... The episodes are 45 minutes long and it runs through one episode, starts the next one, and you’re like, ‘Damn, we got to wait till tomorrow.’”



Fig 3. Non-study participant with TV

<sup>4</sup> Butler, et al. (1997). Physiology of diving of birds and mammals. *Physiological reviews*, 77(3), 837-899.

- Also in Interview 2, James described how he was continuously informed—too linking that to comfort. And, he noted the team was consistent in delivering on what was informed: “Them techs and staff make you feel comfortable. **They take the time to explain everything to you, exactly what’s going to happen, when it’s going to happen, and it just takes that stress point away from what you’re doing. It allows you to, one, relax, and accept the therapy that it is, not knowing if you’re [getting the treatment or control] ... Everything went really smooth in the whole process from the time I got in and out of the chamber ...** [The technician told me,] ‘This is what you are going to expect, let me know if anything hurts or anything and we’ll stop it and then I’ll restart it.’ He was very meticulous ... Everything that they told me from the very beginning, ... everything has been right on ... They got everything in order.”
- In Interview 2, James described medical assessments pre- and post-dive, and confidence in safety: “When I go in there, I get changed, they do my vitals, I get in the bed, they do my vitals, they check me for static, then they roll me on [the gurney] and I just lay there and relax ... [The staff is] concerned 110%, ‘Are you claustrophobic?’ ... They won’t let you [dive] if you’re of any of them things that can be dangerous ... I have 100% confidence, in that if you’re not feeling good one day, they assess you before they even put you in there.”
- The Midpoint Observation reflected James’s gradual relaxation supported by monitoring and entertainment. After receiving his gown, he chatted with a technician about which show he would watch. Following heart rate and oxygen checks, he entered the chamber, fidgeting before relaxing and closing his eyes. When contacted via the chamber phone, he reported no issues. At the end, the technician asked about his movie, and James replied it was enjoyable.

### REFLECTIONS ON HOW JAMES WAS AFFECTED BY STUDY PARTICIPATION

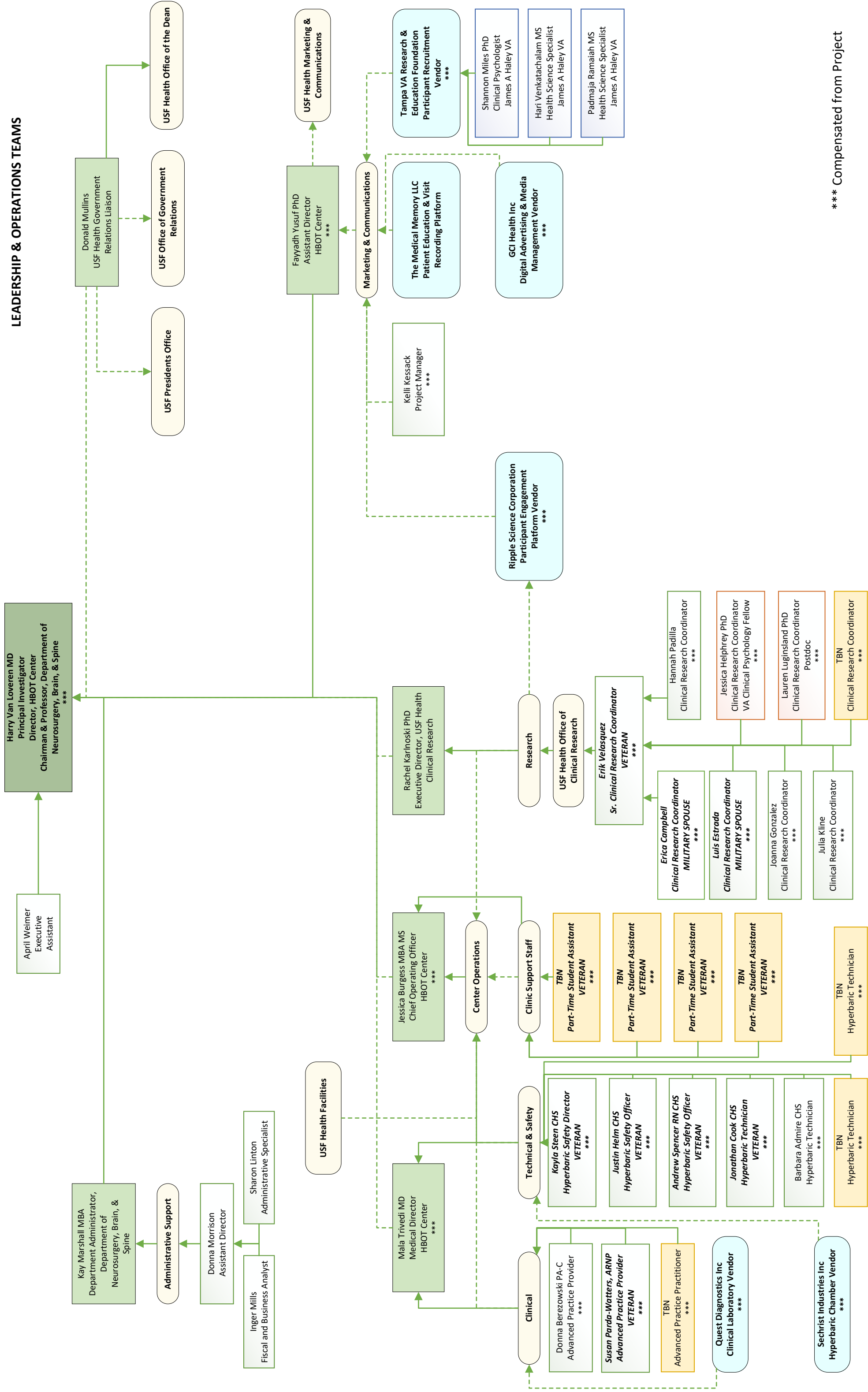
James consistently reported *positive impacts and symptom relief* from the study treatment.

- In Interview 2, James described improvement, “I’ve been in there for three weeks, almost four—I noticed I’ve been less sleepy during the day. I’m able to concentrate more ... It makes me more open to spend time with my family and everything. Makes me more energetic and outgoing ... But from the dive, I can say at the end of the day, ... I am more functional with my family now because I don’t aimlessly wander off into nowhere in the la la land, my wife says.”
- At the Coining Observation, he continued to perceive positive impact. He appeared pleased, hugged a medical staff member, and said, “Ask for my wife’s feedback, this has worked.”

Study participants’ participation is ceremoniously recognized and meaningfully commemorated.

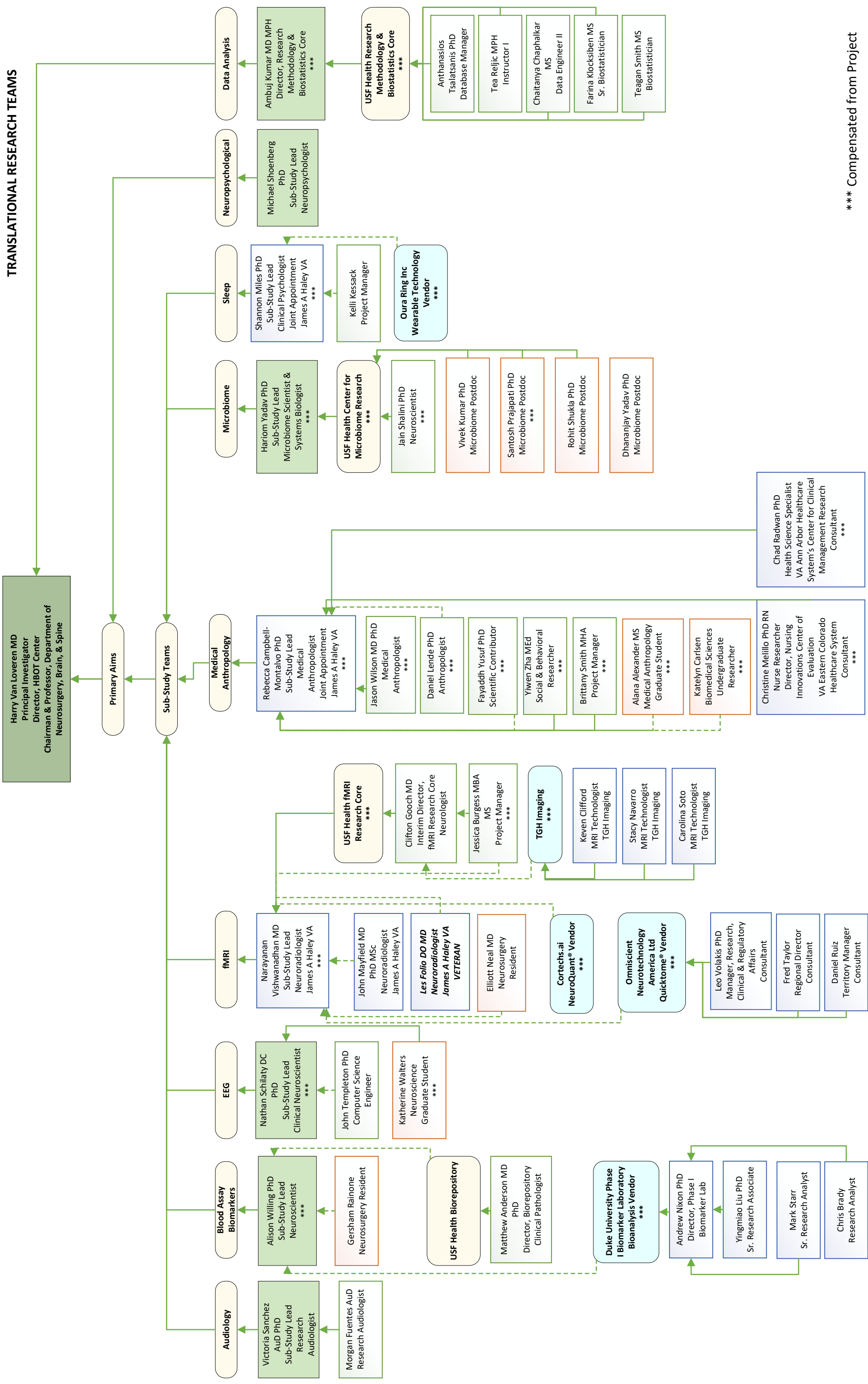
- At the Coining Observation after James’ final dive, the atmosphere was celebratory. A medical staff member turned on a radio and danced as others clapped and smiled. After presenting the coin, a technician thanked James, and staff warmly affirmed that his participation would help other Veterans. Soon after, a medical staff member showed off the collection she has been keeping: the wristbands of each Veteran who had completed all 40 dives.

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