Fiscal Year:	FY 2021	**Task Last Updated:**	FY 07/06/2021
PI Name:	Marshall-Goebel, Karina Ph.D.		
Project Title:	Mechanical and Gravitational Countermeasures to Ocular Changes During Strict Head-Down Tilt Bedrest		
Division Name:	Human Research		
Program/Discipline:			
Program/Discipline--Element/Subdiscipline:			
Joint Agency Name:		**TechPort:**	No
Human Research Program Elements:	(1) **HHC**:Human Health Countermeasures		
Human Research Program Risks:	(1) **SANS**:Risk of Spaceflight Associated Neuro-ocular Syndrome (IRP Rev I)		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Comments:	New affiliation as of fall 2018: KBR/NASA Johnson Space Center, Cardiovascular and Vision Laboratory, Houston; previously at Massachusetts General Hospital		
Project Type:	GROUND	**Solicitation / Funding Source:**	Directed Research
Start Date:	08/21/2020	**End Date:**	08/20/2024
No. of Post Docs:		**No. of PhD Degrees:**	
No. of PhD Candidates:		**No. of Master' Degrees:**	
No. of Master's Candidates:		**No. of Bachelor's Degrees:**	
No. of Bachelor's Candidates:		**Monitoring Center:**	NASA JSC
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Flight Program:			
Flight Assignment:			
Key Personnel Changes/Previous PI:	July 2021 report: Jason Lytle, Jessica Jasien, and Laura Pardon were added as co-investigators to this project.		
COI Name (Institution):	Brunstetter, Tyson O.D., Ph.D. (NASA Johnson Space Center) Greenwald, Scott Ph.D. (KBR/NASA Johnson Space Center) Hargens, Alan Ph.D. (University of California, San Diego) Huang, Alex M.D., Ph.D. (Doheny Eye Institute) Kramer, Larry M.D. (University of Texas Health Science Center at Houston) Laurie, Steven Ph.D. (KBR/NASA Johnson Space Center) Lee, Stuart Ph.D. (KBR/NASA Johnson Space Center) Levine, Benjamin M.D. (University of Texas Southwestern Medical Center) Lovering, Andrew Ph.D. (University of Oregon) Macias, Brandon Ph.D. (NASA Johnson Space Center) Martin, Bryn Ph.D. (Alcyone Therapeutics Inc.) Young, Millennia Ph.D. (NASA Johnson Space Center) Lytle, Jason (KBR/NASA Johnson Space Center) Jasien, Jessica (KBR/NASA Johnson Space Center) Pardon, Laura (KBR/NASA Johnson Space Center)		

Grant/Contract No.:	Directed Research
Performance Goal No.:	
Performance Goal Text:	
Task Description:	The Spaceflight Associated Neuro-ocular Syndrome (SANS) is associated with structural and functional ocular and brain changes and develops in ~2/3rds of astronauts during long-duration spaceflight. Although the etiology of SANS is unknown, a weightlessness-driven headward fluid redistribution relative to the upright position on Earth is hypothesized to be a primary initiating factor. A countermeasure that can successfully reverse this headward fluid shift for multiple hours per day may be needed to prevent SANS. Exposure to 30 days of the spaceflight analog strict 6 degree head-down tilt (HDT) bedrest induces the development of optic disc edema, a hallmark sign of SANS, in 2/3 of subjects; thus, NASA will utilize this platform to test the effectiveness of various countermeasures to prevent or reduce the development of SANS findings. This study will include a control group exposed to 30 days of strict 6 degree HDT. A second group of subjects will be exposed to 6 hours of 25 mmHg lower body negative pressure (LBNP), daily, during 30 days of strict 6 degree HDT bedrest. A third group of subjects will be exposed to 6 hours of upright posture per day, and 6 degree HDT for the remaining 18 h/day. This will help determine if daily exposure to 6 hours total of upright posture, fully reversing the headward fluid for the same duration of use as the LBNP group, is sufficient to prevent SANS findings, and thus can direct future countermeasure studies with respect to the duration needed to successfully prevent SANS. We will assess multiple cerebral, vascular, and ocular outcome measures to determine the effects of 30 days strict 6 degree HDT bedrest, and the ability of daily 6 hour exposure to LBNP or upright positioning to prevent these changes. Specific Aims: 1. To determine if daily exposure to actual (upright posture) and simulated (LBNP) hydrostatic pressure gradients prevents ocular and cerebral structural changes during 30 days of strict 6° head-down tilt bedrest. 2. To determine if daily exposure to actual (upright posture) and simulated (LBNP) hydrostatic pressure gradients prevents ocular functional changes during 30 days of strict 6° head-down tilt bedrest. 3. To determine if daily exposure to actual (upright posture) and simulated (LBNP) hydrostatic pressure gradients prevents vascular and cerebrospinal fluid changes during 30 days of strict 6° head-down tilt bedrest. This bedrest study will be implemented in the :envihab facility at the German Aerospace Center (DLR) in Cologne, Germany.
Rationale for HRP Directed Research:	The Element recommended this task be implemented as a directed task due to the highly constrained nature of this research, which brings to maturation work that was recently completed in a precursor study (the Venous Congestion Countermeasure Study, VCCM). In the VCCM study, this combined team of investigators, comprised of Johnson Space Center (JSC) personnel and external experts, tested different combinations of mechanical countermeasures in a laboratory setting of acute posture changes in order to determine the most efficacious mechanical countermeasure. The identified countermeasure now needs to be tested on subjects exposed to 30-days of strict 6º head-down tilt (HDT) bedrest, with an expectation that this will ultimately lead to testing of the countermeasure during spaceflight. Time constraints are a secondary rationale, as the bedrest study is slated to start in the spring of 2021, and NASA's Research Operations Integration Element requires the proposed science immediately in order to finalize implementation.
Research Impact/Earth Benefits:	
Task Progress:	In this reporting period, we have coordinated with the Research Operations and Integration element to develop the Integrated Research Document that describes the study schedule and implementation, procured hardware and consumables, shipped equipment to the DLR (targeted delivery to DLR by August 2021), developed and prepared study protocols, developed and prepared training materials for the DLR, and intend to hold multiple virtual training sessions with the DLR staff by the end of this reporting period. Additional preparations and training materials have been developed to support the virtual nature of the trainings with DLR. Furthermore, we have modified and tested our ultrasound and optical coherence tomography data analysis programs to accommodate the SANS bedrest study design for data analysis. We have obtained NASA Institutional Review Board (IRB) approval and anticipate completing multiple human-in-the-loop trainings and dry run experiments with the DLR prior to the first campaign of the study. The first campaign of this bedrest study (n=12) is scheduled to begin data collection in September 2021 and end in November 2021.
Bibliography Type:	Description: (Last Updated: 07/08/2021)
Abstracts for Journals and Proceedings	Marshall-Goebel K, Laurie S, Lee S. Greenwald S, Pardon L, Lovering A, Huang A, Martin B, Brunstetter T, Young M, Levine B, Hargens A, Kramer L, Macias B. "Mechanical and Gravitational Countermeasures to Ocular Changes during Strict Head-Down Tilt Bedrest." Poster presentation. 2021 NASA Human Research Program Investigators' Workshop, Virtual, February 1-4, 2021. Abstracts. 2021 NASA Human Research Program Investigators' Workshop, Virtual, February 1-4, 2021. , Feb-2021