

<b>Fiscal Year:</b>	FY 2021	<b>Task Last Updated:</b>	FY 12/04/2020
<b>PI Name:</b>	Macias, Brandon Ph.D.		
<b>Project Title:</b>	Investigating Structure and Function of the Eye		
<b>Division Name:</b>	Human Research		
<b>Program/Discipline:</b>			
<b>Program/Discipline--Element/Subdiscipline:</b>			
<b>Joint Agency Name:</b>		<b>TechPort:</b>	No
<b>Human Research Program Elements:</b>	(1) <b>HHC:</b> Human Health Countermeasures		
<b>Human Research Program Risks:</b>	(1) <b>SANS:</b> Risk of Spaceflight Associated Neuro-ocular Syndrome (SANS)		
<b>Space Biology Element:</b>	None		
<b>Space Biology Cross-Element Discipline:</b>	None		
<b>Space Biology Special Category:</b>	None		
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<b>PI Organization Type:</b>	NASA CENTER	<b>Phone:</b>	281-483-2026
<b>Organization Name:</b>	NASA Johnson Space Center		
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<b>City:</b>	Houston	<b>State:</b>	TX
<b>Zip Code:</b>	77058	<b>Congressional District:</b>	36
<b>Comments:</b>	NOTE: Became civil servant fall 2020; previously KBR/NASA Johnson Space Center. Prior to that until 2016, was at the University of California, San Diego.		
<b>Project Type:</b>	FLIGHT	<b>Solicitation / Funding Source:</b>	2017-2018 HERO 80JSC017N0001-BPBA Topics in Biological, Physiological, and Behavioral Adaptations to Spaceflight. Appendix C
<b>Start Date:</b>	01/30/2019	<b>End Date:</b>	01/24/2026
<b>No. of Post Docs:</b>	0	<b>No. of PhD Degrees:</b>	0
<b>No. of PhD Candidates:</b>	0	<b>No. of Master' Degrees:</b>	0
<b>No. of Master's Candidates:</b>	0	<b>No. of Bachelor's Degrees:</b>	0
<b>No. of Bachelor's Candidates:</b>	0	<b>Monitoring Center:</b>	NASA JSC
<b>Contact Monitor:</b>	Stenger, Michael	<b>Contact Phone:</b>	281-483-1311
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<b>Flight Program:</b>			
<b>Flight Assignment:</b>	NOTE: End date changed to 1/24/2026 per HHC element/JSC (Ed., 4/8/21) NOTE: End date changed to 9/30/2025 per PI (Ed., 12/21/19)		
<b>Key Personnel Changes/Previous PI:</b>	December 2020 report: Key Personnel Added to Project Team: Laura Pardon, Jessica Jasien, Jason Lytle, Karina Marshall-Goebel; Key Personnel Removed from Project Team: Michael Stenger, Alan Feiveson, Linda Loerch.		
<b>COI Name (Institution):</b>	Brunstetter, Tyson O.D., Ph.D. ( NASA Johnson Space Center ) Hargens, Alan Ph.D. ( University of California, San Diego ) Huang, Alex M.D., Ph.D. ( Doheny Eye Institute ) Karanjia, Rustum M.D., Ph.D. ( Doheny Eye Institute ) Laurie, Steven Ph.D. ( KBR/NASA Johnson Space Center ) Martin, Bryn Ph.D. ( University of Idaho, Moscow ) Sadda, Srinivas M.D. ( Doheny Eye Institute ) Smith, Scott Ph.D. ( NASA Johnson Space Center ) Zwart, Sara Ph.D. ( University of Texas, Galveston )		

	<p>Lee, Stuart Ph.D. ( KBR/NASA Johnson Space Center )  Gibson, Charles O.D. ( Coastal Eye Associates )  Kramer, Larry M.D. ( University of Texas Health Science Center, Houston )  Greenwald, Scott Ph.D. ( KBR/NASA Johnson Space Center )  Jasien, Jessica Ph.D. ( JesTech./NASA Johnson Space Center )  Lytle, Jason Ph.D. ( KBR/NASA Johnson Space Center )  Marshall-Goebel, Karina Ph.D. ( KBR/NASA Johnson Space Center )  Pardon, Laura O.D., Ph.D. ( KBR/NASA Johnson Space Center )</p>
<b>Grant/Contract No.:</b>	Internal Project
<b>Performance Goal No.:</b>	
<b>Performance Goal Text:</b>	
<b>Task Description:</b>	<p>This proposal will identify if ocular structure and function alterations occur at a greater frequency and magnitude during one-year missions compared to six-month and six-week expeditions and whether the recovery profile is dependent upon mission duration. In addition, this project will determine if changes in vascular structure and function are greater after one-year missions and contribute to alterations in ocular structure and function. The identification of structural and functional changes will provide NASA the information necessary to inform the risk posture for future interplanetary expeditions with duration of up to three years and to identify possible countermeasures.</p> <p><b>SPECIFIC AIMS</b></p> <p>Conducting Spaceflight Associated Neuro-ocular Syndrome (SANS) research on one-year, six-month, and short-duration (2-month) crew members will enable us to objectively generate data to help NASA determine if and how SANS symptoms worsen with mission duration. These new data from longer missions will enable us to develop a non-linear trend model that can be extrapolated to make predictions for even longer missions, up to three years, and therefore help NASA to define the risk posture for future interplanetary expeditions, and to identify possible countermeasures by the following specific aims:</p> <p>Specific Aim 1: To determine if ocular structural changes develop to a greater degree (frequency or magnitude) during long-duration one-year spaceflight missions compared to findings during shorter length missions and if recovery is prolonged after longer missions.</p> <p>Specific Aim 2: To determine if ocular vascular structure is altered to a greater degree during long-duration one-year spaceflight missions, and if recovery is more prolonged.</p> <p>Specific Aim 3: To determine if ocular function is altered to a greater degree during long duration one-year spaceflight missions, and the recovery profile.</p> <p>Specific Aim 4: To determine if measures of vascular structure and function are altered to a greater degree during long-duration one-year spaceflight missions and if these vascular adaptations correlate with alterations in ocular structure and function.</p> <p><b>RELEVANCE &amp; MAP TO HUMAN RESEARCH ROADMAP</b></p> <p>This multi-project proposal is in response to NASA research announcement Human Exploration Research Opportunities (HERO), 80JSC017N0001-BPBA, Appendix C, Topic 1: Analyses of the Temporal Nature of Human Adaptation to Long-Duration Low-Earth Orbit Mission Virtual NASA Specialized Center of Research (VNSCOR). This proposal addresses multiple Human Research Program (HRP) Integrated Research Plan Gaps, including: SANS101: Determine the relationship between fluid shifts (intravascular, interstitial, CSF) and ocular manifestations in astronauts during spaceflight. SANS102: Determine the relationship between the fluid-shifts induced ocular changes and fluid shifts in the CNS, including whether elevated intracranial pressure or brain edema play a role.</p>
<b>Rationale for HRP Directed Research:</b>	
<b>Research Impact/Earth Benefits:</b>	<p>The Investigating Structure and Function of the Eye (iSAFE) research study will advance NASA's understanding of Spaceflight associated neuro-ocular syndrome (SANS), an important human health and performance risk, by quantifying how ocular alterations develop as a function of spaceflight duration and identifying causative mechanisms. Results from this study are anticipated to lead to a temporal model of SANS progression during long-term missions and to inform the development of countermeasures. Given the unique environment of the International Space Station, commonly used ophthalmic instruments are being implemented in novel operational environments. This work may lead to clinical practice adopting these new hardware, software, or protocol elements, benefiting patients on Earth. SANS shares characteristics with several terrestrial ophthalmic diseases, such as papilledema, and iSAFE study results could provide new insights into mechanisms underlying these conditions.</p>
	<p>Within this reporting period:</p> <ul style="list-style-type: none"> <li>• The iSAFE Principal Investigator (PI) team has worked with NASA Research Operations and Integration (ROI) Element to integrate this project into the Compliment of Integrated Protocols for Human Exploration Research on varying mission durations (CIPHER) project. The CIPHER study has received select-for-flight approval by the Human Research Program Control Board.</li> <li>• We completed an informed consent briefing (ICB) with a crewmember while iSAFE had a select-for-flight status for the 6-month duration mission cohort. This status was reversed due to flight schedule conflicts, at which point iSAFE was integrated into the prime CIPHER study, as mentioned above.</li> <li>• Supported the CIPHER Study PI "Face-to-Face" meeting (1/31/2020), which represented a major step toward coordinating the full complement of studies. Based on the outcome of this meeting, we updated our Institutional Review Board documents and experiment procedures to ensure compatibility and appropriate data sharing with the other studies.</li> <li>• Optical biometry hardware was acquired for ground baseline data collection.</li> </ul>

Task Progress:	<ul style="list-style-type: none"> <li>• The FORUM electronic medical records system was implemented for analyzing and securely storing visual field analysis data.</li> <li>• Worked with ROI to achieve milestones that have made research hardware (i.e., Electroretinography and pneumotonometry systems) flight ready.</li> <li>• Worked with ROI to baseline the Experimental Document for iSAFE 6-month cohort.</li> <li>• The plans for iSAFE were presented at the 2020 Human Research Program Investigators' Workshop in Galveston, TX.</li> <li>• Substantial progress has been made towards completing the iSAFE data analysis plan.</li> <li>• Substantial progress has been made towards completing the Standard operating procedures (SOPs) and workflows for the collection of electroretinography, optical coherence tomography, pneumotonometry (intraocular pressure), and visual field analysis data.</li> <li>• We supported presentations to control boards to earn an accelerated select for flight status for initiating research with the 6-month duration cohort.</li> <li>• The drafting of operator logs to capture activity during ground and in flight data collection sessions is in progress.</li> <li>• Substantial progress has been made in drafting of the iSAFE Test Readiness Review document.</li> </ul>
Bibliography Type:	Description: (Last Updated: 04/04/2024)
Abstracts for Journals and Proceedings	<p>Macias BR, Greenwald SH, Brunstetter R, Feiveson A, Hargens A, Huang A, Karanjia R, Laurie SS, Lee SMC, Marshall-Goebel K, Martin BA, Kramer LA, Sadda S, Smith SM, Zwart SR, Stenger MB. "Investigating structure and function of the eye (iSAFE)." Presented at the 2020 NASA Human Research Program Investigators' Workshop, Galveston, TX, January 27-30, 2020.</p> <p>Abstracts. 2020 NASA Human Research Program Investigators' Workshop, Galveston, TX, January 27-30, 2020. , Jan-2020</p>