Fiscal Year:	FY 2013	**Task Last Updated:**	FY 08/23/2012
PI Name:	Williams, Michael A. M.D.		
Project Title:	Comparison of Continuous Non-Invasive and Invasive Intracranial Pressure Measurement		
Division Name:	Human Research		
Program/Discipline:	NSBRI		
Program/Discipline--Element/Subdiscipline:	NSBRI--Smart Medical Systems and Technology Team		
Joint Agency Name:		**TechPort:**	No
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Human Research Program Risks:	(1) **SANS**:Risk of Spaceflight Associated Neuro-ocular Syndrome (SANS)		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Comments:			
Project Type:	Ground	**Solicitation / Funding Source:**	2011 Crew Health NNJ11ZSA002NA
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No. of PhD Candidates:		**No. of Master' Degrees:**	
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No. of Bachelor's Candidates:		**Monitoring Center:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
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Flight Assignment:			
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Hamilton, Douglas (Wyle Science, Technology and Engineering Group) Voss, Susan (Smith College)		
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	Introduction: Recently, astronauts in long-duration spaceflight have been found to have a syndrome consisting of swelling of the optic nerve, impaired vision, and elevated cerebrospinal fluid pressure (also known as intracranial pressure [ICP]) via lumbar puncture (LP), which is similar to the syndrome of idiopathic intracranial hypertension (IIH). It is not possible to perform an LP on astronauts in space. Noninvasive methods of estimating ICP exist but have not been tested against continuous ICP methods in a patient cohort that is physiologically similar to that of astronauts. Accurately determining the presence or absence of ICP elevation during spaceflight is critical (1) for determining if ICP elevation causes these abnormalities, thus identifying the need for appropriate prevention and treatment and (2) for monitoring astronauts during spaceflight to determine if they are at risk for eye abnormalities and visual impairment because of ICP elevation. Primary Objective: Determine the validity, reliability, accuracy, and precision of two noninvasive methods of ICP		

Task Description:	measurement (tympanic membrane displacement [TMD, Marchbanks Measurements Systems, UK] and distortion product otoacoustic emissions [DPOAE]) in comparison to a reference standard, invasive ICP measurement, in human subjects undergoing diagnostic ICP monitoring. Methods: This is a prospective research protocol involving human patients. Eligibility criteria include (1) adults ages 18–65 years, (2) clinically indicated need for continuous ICP monitoring for the diagnosis of hydrocephalus, IIH, or shunt malfunction, or (3) clinically indicated need for CSF-infusion testing for the diagnosis of hydrocephalus or IIH. Invasive ICP methods include (1) spinal catheter insertion and fluid-coupled external transducers for patients with hydrocephalus, IIH, (2) insertion of a 25-gauge needle into the shunt reservoir and fluid-coupled external transducers for patients with shunt malfunction, and (3) CSF-infusion testing, which will use a standardized automated system, Likvor Celda® System (http://www.likvor.com) that has been validated in clinical use in Sweden. Noninvasive ICP methods include TMD method and DPOAE. Protocols: (1) Continuous ICP Monitoring. Simultaneous measurement of invasive and noninvasive ICP will be made in the following conditions: (a) Awake in the supine, sitting, standing, and 6-degree head-down position, (b) Asleep in the patient's preferred position, which will be either supine or with slight elevation of the head of the bed. Data will be analyzed in intervals that correspond to the shortest amount of time necessary for each noninvasive method to provide reliable data. (2) CSF-Infusion Testing. CSF-infusion testing will use the continuous-pressure method, in which ICP is regulated to 6 predetermined pressure levels in steps of 3 mmHg. Noninvasive ICP will be measured at each pressure level, allowing controlled, identical pressure range for evaluation in each patient. Significance: This proposal specifically addresses NASA's High Priority Research Area in Visual Impairment and Intracranial Pressure. The validation of noninvasive ICP methods is of utmost importance for the goal of measuring ICP in spaceflight, which is essential for the health and safety of astronauts in long-duration spaceflight. The noninvasive methods must be shown to be accurate over the pressure ranges expected in normal individuals (0–15 mmHg) and in those with an IIH-like presentation post-flight (15–40 mmHg). Without validation in the physiologic range expected in normal individuals and those with intracranial hypertension, noninvasive ICP measurement methods cannot be selected for advancement through Technology Readiness Levels to be designed for use in an exploration mission (TRL-6).
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	
Task Progress:	New project for FY2013.
Bibliography Type:	Description: (Last Updated: 08/24/2020)