Fiscal Year:	FY 2015	**Task Last Updated:**	FY 11/04/2015
PI Name:	McCann, Corey M. M.D., Ph.D.		
Project Title:	Software Enabled Therapeutics for Psychiatry, Neurology, and Pain		
Division Name:	Human Research		
Program/Discipline:	NSBRI		
Program/Discipline--Element/Subdiscipline:	NSBRI--Neurobehavioral and Psychosocial Factors Team		
Joint Agency Name:		**TechPort:**	Yes
Human Research Program Elements:	(1) **BHP**:Behavioral Health & Performance (archival in 2017)		
Human Research Program Risks:	(1) **BMed**:Risk of Adverse Cognitive or Behavioral Conditions and Psychiatric Disorders (2) **Sleep**:Risk of Performance Decrements and Adverse Health Outcomes Resulting from Sleep Loss, Circadian Desynchronization, and Work Overload		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Zip Code:	02111	**Congressional District:**	7
Comments:			
Project Type:	GROUND	**Solicitation / Funding Source:**	NSBRI-RFA-SMARTCAP
Start Date:	08/01/2014	**End Date:**	07/31/2015
No. of Post Docs:	0	**No. of PhD Degrees:**	0
No. of PhD Candidates:	0	**No. of Master' Degrees:**	0
No. of Master's Candidates:	0	**No. of Bachelor's Degrees:**	0
No. of Bachelor's Candidates:	0	**Monitoring Center:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
Flight Program:			
Flight Assignment:	NOTE: Change in period of performance to 8/1/2014-7/31/2015 (originally 7/1/14-6/30/15), per NSBRI (Ed., 11/9/15)		
Key Personnel Changes/Previous PI:			
COI Name (Institution):			
Grant/Contract No.:	NCC 9-58-NBPF03601		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	Overview On exploration missions, astronauts will not have access to comprehensive health care services for periods of two years, and possibly longer. This exposes the astronauts to several risks: 1) Risk of adverse behavioral conditions and psychiatric disorders. 2) Risk of performance decrements due to inadequate cooperation, coordination, communication, and psychological adaptation within a team. 3) Risk of acute and late Central Nervous System (CNS) effects from radiation exposure. This includes CNS damage leading to acute and/or late changes in motor function, behavior, or neurological disorders. 4) Risk of performance errors due to fatigue resulting from sleep loss, circadian desynchronization, extended wakefulness, and work overload. The overarching goal of this pilot project was to design and develop the PEAR eFormulation System – a suite of digital eHealth applications connected to a predictive analytics platform, designed to work in combination with psychoactive medications to address anxiety, depression, cognitive function, as well as other CNS indications such as sleep disorders. The combination of eHealth and pharmaceutical interventions provides the ability to impact both brain chemistry and cognitive experience simultaneously, providing a synergistic approach to addressing CNS problems, and a means to dynamically adjust interventions to better match an individuals response to medication and to eHealth interventions. The PEAR System functions to mitigate several of the significant behavioral health and performance risks associated with spaceflight. The system also provides a research platform with full data integration, data visualization, and predictive analytics that can be used to evaluate the effectiveness of pharmaceutical and eHealth interventions on mood disorders, cognitive performance deficits, and sleep disorders. Project Aims/Objectives This project is responsive to the National Space Biomedical Research Institute (NSBRI) Neurobehavioral and Psychosocial Factors (NBPF) Team goals of: 1) Mitigating the risks of stress, anxiety, and depression in spaceflight by development of digital eHealth tools to monitor and provide supportive interventions that work synergistically with medications to address mood disorders via evidenced based approaches, such as cognitive behavioral therapy (CBT). 2) Mitigate risks of cognitive performance deficits in space by development of techniques to prevent, detect, and counter cognitive deficits due to radiation and fatigue in space by development of digital eHealth tools to monitor and provide supportive interventions that work synergistically with medications to address cognitive disorders via evidenced based approaches. 3) Mitigation of risk of performance errors due to sleep loss and circadian desynchronization by development of digital eHealth tools to monitor and provide supportive interventions that work synergistically with medications to address sleep disorders via evidenced based approaches. Key Findings The main results of the project are as follows: 1) Five eHealth apps were developed to address problems identified as risks during extended spaceflight, including anxiety, depression, diminished cognitive function, and sleep dysfunction. 2) A server-based platform was developed to coordinate and manage the eHealth apps, and to provide the predictive analytics required to manage digital health therapy used in combination with pharmaceutical intervention. 3) In addition to providing effective interventions, the apps and platform support the collection and analysis of real-time behavioral and biometric data. This information is to dynamically adjust interventions. 4) The system provides an extended analysis and reporting capability, and can support all aspects of intervention management and basic research. Impact of Key Findings The development project is complete, and will have significant impact. The project fostered the development of the first system to combine behavioral medicine and CNS focused digital health apps with pharmaceutical interventions, including biometric and behavioral measurements, in an integrated manner so as to provide dynamic management of interventions and protocols via a server-based predictive analytics platform. The current Pear eFormulation System is focused on specifically addressing the problems of anxiety, depression, cognitive function, and sleep disorders. However, the PEAR System can and will be extended to address other significant problems in behavioral medicine, mental health, and CNS disease, including: substance abuse, weight management, hypertension, pain management, Post Traumatic Stress Disorder, Traumatic Brain Injury, stroke, schizophrenia, and others. The PEAR System pioneers the way for a new-generation of integrated therapeutic approaches, and affords a pathway for providing more effective interventions at a lower cost, and with enhanced clinical efficacy. In this manner the current project helps to addresses a significant societal problem: Our healthcare system requires next generation therapeutics that provide enhanced clinical safety and efficacy – interventions that are efficient and can reduce the overall cost of mental health care. This need is particularly acute with regard to new therapies and preventive approaches in the field of behavioral medicine, mental health, and CNS disease. The US currently spends ~ $1.3 Trillion per year on brain-related diseases. Yet 80% of the world population is currently unserved or underserved. Few new therapies are set to come to market for CNS related diseases as drug development has been extremely difficult and time consuming, with many late phase and high profile clinical failures. Combining digital eHealth applications with pharmaceutical interventions generates improved clinical results, promotes adherence and compliance, and provides a reimbursement mechanism to promote adoption.
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	The eHealth systems and paradigms developed for this project have significant clinical value beyond use in Spaceflight. The project fostered the development of the PEAR eFormulation System -- a digital eHealth system that combines behavioral medicine / CNS focused digital health apps with pharmaceutical interventions, including biometric and behavioral measurements. The resulting system provides dynamic management of interventions and protocols via a server-based predictive analytics platform. The current system is focused on the problems of anxiety, depression, cognitive function, and sleep disorders. However, the PEAR System can be extended to address other significant problems in behavioral medicine, mental health, and CNS disease, including: substance abuse, weight management, hypertension, pain management, Post Traumatic Stress Disorder, Traumatic Brain Injury, stroke, schizophrenia, and others. Few new therapies are set to come to market for these diseases, as drug development has been extremely difficult and time consuming, with many late phase and high profile clinical failures. eHealth and pharmaceutical combinations impact both brain chemistry and cognitive experience simultaneously, providing a synergistic approach to addressing clinical problems in behavioral medicine, mental health, and CNS disease. The PEAR System pioneers the way for a new-generation of integrated therapeutic approaches, and affords a pathway for providing more effective interventions at a lower cost, and with enhanced clinical efficacy. In this manner the current project addresses a significant societal problem: our healthcare system urgently requires next generation therapeutics that provide enhanced clinical safety and

	efficacy – interventions that are clinically effective and can reduce the overall cost of mental health care. This need is particularly acute with regard to new therapies and preventive approaches in the field of behavioral medicine, mental health, and CNS disease. The US currently spends ~ $1.3 Trillion per year on brain-related diseases. Yet 80% of the world population is currently unserved or underserved. Few new therapies are set to come to market for CNS related diseases as drug development has been extremely difficult and time consuming, with many late phase and high profile clinical failures. Combining digital eHealth applications with pharmaceutical interventions generates improved clinical results, promotes adherence and compliance, and provides a reimbursement mechanism to promote adoption.
Task Progress:	The overarching goal of the project was to develop a server-based platform linked to five digital eHealth interventions that work synergistically with psychoactive medications to address anxiety, depression, and cognitive function, as well as several other CNS indications such as sleep disorders. The project accomplished all of the design and development goals, and is currently undergoing user testing and iterative refinement. The main results of the project are as follows: 1) Five eHealth apps were developed to address problems identified as risks during extended spaceflight, including anxiety, depression, diminished cognitive function, and sleep dysfunction. 2) A server-based platform was developed to coordinate and manage the eHealth apps, and to provide the analytics required to manage digital health therapy used in combination with pharmaceutical intervention. 3) In addition to providing effective interventions, the apps and platform support the collection and analysis of real-time behavioral and biometric data, and can use this information to dynamically adjust interventions. 4) The system provides an extended analysis and reporting capability, and can support all aspects of intervention management and basic research.
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