Fiscal Year:	FY 2019	**Task Last Updated:**	FY 03/22/2019
PI Name:	Wotring, Virginia Ph.D.		
Project Title:	Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms, and Adverse Effects During Missions		
Division Name:	Human Research		
Program/Discipline:			
Program/Discipline--Element/Subdiscipline:			
Joint Agency Name:		**TechPort:**	No
Human Research Program Elements:	(1) **ExMC**:Exploration Medical Capabilities		
Human Research Program Risks:	(1) **Medical Conditions**:Risk of Adverse Health Outcomes and Decrements in Performance Due to Medical Conditions that occur in Mission, as well as Long Term Health Outcomes Due to Mission Exposures (2) **Pharm**:Risk of Ineffective or Toxic Medications During Long-Duration Exploration Spaceflight		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
PI Email:	Virginia.Wotring@bcm.edu	**Fax:**	FY
PI Organization Type:	UNIVERSITY	**Phone:**	
Organization Name:	Baylor College of Medicine		
PI Address 1:	Center for Space Medicine		
PI Address 2:	6500 Main St, Suite 910		
PI Web Page:			
City:	Houston	**State:**	TX
Zip Code:	77030	**Congressional District:**	9
Comments:	PI formerly with Universities Space Research Association until fall 2015.		
Project Type:	FLIGHT	**Solicitation / Funding Source:**	Directed Research
Start Date:	05/26/2016	**End Date:**	11/30/2018
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
Contact Monitor:	Antonsen, Erik	**Contact Phone:**	281.483.4961
Contact Email:	erik.l.antonsen@nasa.gov		
Flight Program:	ISS		
Flight Assignment:	NOTE: Grant ended 11/30/2018 per PI and NSSC information; original end date was 5/25/2021 (Ed., 2/26/19)		
Key Personnel Changes/Previous PI:	March 2019 report: None.		
COI Name (Institution):	Smith, LaRona M.S.,R.N. (JES Tech/NASA Johnson Space Center)		
Grant/Contract No.:	NNX16AK78G		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	NOTE: Continuation of "Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms, and Adverse Effects During Missions" (Internal Project) with the same investigator, Dr. Virginia Wotring, due to PI move to Baylor College of Medicine. Do medications used during spaceflights work the same as they do on Earth? This single question underlies most of the unknowns within NASA's Human Research Program Risk of Clinically Relevant Unpredicted Effects of Medication. During spaceflight, the body undergoes a number of physiological changes that are expected to result in altered interactions with administered medications, but it is not yet known if, or to what extent, these actually occur. The potential for therapeutically relevant alteration in either pharmacokinetics (how the body handles administered medications) or pharmacodynamics (how administered medications act upon the body) has long been a concern. This observational epidemiological study is a proactive step toward addressing this issue via regular direct questioning of crewmember volunteers, a model that the Johnson Space Center (JSC) Nutritional Biochemistry Discipline has proven to be both feasible and useful. A tablet- or handheld device-based questionnaire will be used to permit fast and efficient collection of data regarding crewmembers' medication use on a near real-time basis, eliminating the current problems associated with recall over periods of weeks. Specific questions regarding medication use (somewhat different from the questions that physicians ask regarding patient health) will be asked of each participating crewmember. The data collection process will be streamlined by using a flexibly programmed computerized survey application that leverages the limited medication choices aboard, the doses available, typical dosing frequency, and side effects associated with each medication to provide an individualized short questionnaire for each medication use by the crewmember. Coded (de-identified) data will be delivered weekly to a secure server on the ground for analysis by study investigators. Post-flight (after re-adaptation to Earth's gravity), each participating crewmember will repeat recording their medication usage, so that their ground medication usage frequencies, doses, and perceptions may be compared to those recorded during flight.
Rationale for HRP Directed Research:	This research is directed because it contains highly constrained research, which requires focused and constrained data gathering and analysis that is more appropriately obtained through a non-competitive proposal.
Research Impact/Earth Benefits:	The study demonstrated a significant increase in the amount of medication usage information collected. Self-reports of medication use collected by the app were higher than found in medical records, by more than an order of magnitude. This finding may now be used in determining new medical operations requirements for the collection of this type of information on future missions.
Task Progress:	This study was proposed to Human Research Program (HRP) as a Directed study to address 3 gaps in pharmacology that had insufficient data: medication use, pharmacokinetics, and pharmacodynamics. It was designed to collect medication use information relevant for researchers as nonintrusively as possible from crewmembers. A total of 24 subjects was requested for participation, but the study was ended by NASA at n=5. The crew data show a pattern of medication use similar to what has been previously reported, with sleep disturbances and muscle/joint pain driving most self-administration. Two subjects treated lengthy skin problems, while 3 used chronic treatments to protect the heart or reduce cholesterol. Crew also used the app to note Drug Tolerance Testing, medication holiday requested in research protocol, and to share personal data with a flight surgeon. Crew provided usability feedback critical of app design and implementation, items that could certainly be altered in after coordinated input from users and NASA operational staff. The study is now complete. Study hardware (iPads) have been wiped and excessed through Johnson Space Center's typical procedures. Data files have been prepared for submission to Lifetime Surveillance of Astronaut Health (LSAH). Preliminary, programmatic level results were presented to international colleagues at the International Society for Gravitational Physiology meeting in Noordwijk, The Netherlands, 17-22 June 2018. Both the abstract and presentation were export controlled. Attendance at this meeting permitted the Principal Investigator (PI) to compare and contrast the Dose Tracker app itself with European Space Agency efforts along similar lines. The same presentation was given at the International Space Station (ISS) Research & Development Conference in San Francisco, CA, 21-26 July 2018. Attendance at this meeting permitted the PI to discuss app development for ISS with other researchers developing software for the ISS now and in the future.
Bibliography Type:	Description: (Last Updated: 12/24/2019)
Abstracts for Journals and Proceedings	Wotring V, Smith L. "Dose Tracker: an iOS app for collection of medication use data from volunteer crewmembers on the International Space Station." 39th International Society for Gravitational Physiology (ISGP) & European Space Agency (ESA) Life Sciences Meeting, Noordwijk, Netherlands, June 18-22, 2018. Front Physiol Conference Abstract: 39th ISGP Meeting & ESA Life Sciences Meeting, Published Online: 16 Jan 2019. https://doi.org/10.3389/conf.fphys.2018.26.00047 , Jan-2019
Articles in Peer-reviewed Journals	Wotring VE, Smith LK. "Dose tracker application for collecting medication use data from International Space Station crew. " Aerosp Med Hum Perform. 2020 Jan 1;91(1):41-5. https://doi.org/10.3357/AMHP.5392.2020 ; PubMed PMID: 31852573 , Jan-2020