

<b>Fiscal Year:</b>	FY 2017	<b>Task Last Updated:</b>	FY 03/15/2017
<b>PI Name:</b>	Wotring, Virginia Ph.D.		
<b>Project Title:</b>	Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms, and Adverse Effects During Missions		
<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>ExMC</b> :Exploration Medical Capabilities		
<b>Human Research Program Risks:</b>	(1) <b>Medical Conditions</b> :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) <b>Pharm</b> :Risk of Ineffective or Toxic Medications During Long-Duration Exploration Spaceflight		
<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>	UNIVERSITY	<b>Phone:</b>	
<b>Organization Name:</b>	Baylor College of Medicine		
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<b>City:</b>	Houston	<b>State:</b>	TX
<b>Zip Code:</b>	77030	<b>Congressional District:</b>	9
<b>Comments:</b>	PI formerly with Universities Space Research Association until fall 2015.		
<b>Project Type:</b>	Flight	<b>Solicitation / Funding Source:</b>	Directed Research
<b>Start Date:</b>	05/26/2016	<b>End Date:</b>	11/30/2018
<b>No. of Post Docs:</b>	<b>No. of PhD Degrees:</b>		
<b>No. of PhD Candidates:</b>	<b>No. of Master' Degrees:</b>		
<b>No. of Master's Candidates:</b>	<b>No. of Bachelor's Degrees:</b>		
<b>No. of Bachelor's Candidates:</b>	<b>Monitoring Center:</b> NASA JSC		
<b>Contact Monitor:</b>	Antonsen, Erik	<b>Contact Phone:</b>	281.483.4961
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<b>Flight Program:</b>	ISS		
<b>Flight Assignment:</b>	NOTE: Grant ended 11/30/2018 per PI and NSSC information (Ed., 2/26/19)		
<b>Key Personnel Changes/Previous PI:</b>	March 2017 report: Kyla Cook added as BCM (Baylor College of Medicine) Project Manager and Data Analyst.		
<b>COI Name (Institution):</b>	Smith, LaRona M.S.,R.N. ( JES Tech/NASA Johnson Space Center )		
<b>Grant/Contract No.:</b>	NNX16AK78G		
<b>Performance Goal No.:</b>			
<b>Performance Goal Text:</b>			

Task Description:	<p>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.</p> <p>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.</p>
Rationale for HRP Directed Research:	<p>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.</p>
Research Impact/Earth Benefits:	
Task Progress:	<p><b>Results:</b></p> <p>Data collection is ongoing. We have currently enrolled/obtained consent for 6 subjects. In FY16, 4 subjects completed inflight data collection and 2 subjects completed ground data collection (1 subject has completed both ground and flight data collection). Data collection is still ongoing, with 2 subjects currently completing flight data collection and 3 subjects completing ground data collection. Thus far, we have collected more over 224 weeks of medication usage data (128 weeks inflight, 96 weeks on the ground); this includes over 5800 recorded medication entries (3049 inflight, 2717 ground), for an average of 961 entries per subject (453 inflight, 508 ground).</p> <p><b>Discussion:</b></p> <p>As data collection is still ongoing, we are unable to discuss detailed results. However, the medication usage data captured by Dose Tracker has already surpassed previous medication logging methods used for crewmembers, as measured by number of reports of medication use (Wotring, 2015). Although still early in the data collection phase, the inflight average of 453 medication entries per subject is over 38 times greater than the 12 medication entries per subject reported in crew medication records (Wotring, 2015). Additionally, Dose Tracker has collected 49 reports of no medication use (in a given week of data collection), providing positive confirmation that a crewmember is not using medications, instead of relying on the (possibly incorrect) assumption that no data equals no medication usage.</p> <p>In FY16, we developed, tested, and released updated versions of both ground and flight Dose Tracker software, correcting several software bugs and renewing the iOS provisioning profile. Another provisioning profile update is planned for FY17. We met with JSC software developers and ExMC (Exploration Medical Capabilities) element staff to discuss future updates/changes to Dose Tracker, including improvements to the app's usability and the potential transition to a web application.</p> <p>Dose Tracker has currently paused recruiting new subjects at ExMC Element Scientists's decision, in order to conduct a usability review of the software with crewmembers. We are currently conducting a review of the Dose Tracker application and exploring ways to improve the app's usability, working with Kerry Maguire of ExMC. We plan to leverage this software update by also preparing a web application version of Dose Tracker, thus enabling use of any computer, rather than being restricted to iPad hardware. As a result of the pause in recruitment, 3 subjects who previously consented and had planned to started ground data collection in FY16 have now dropped the study.</p> <p>At the request of a subject, we have started data sharing with their JSC flight surgeon, providing detailed weekly medication usage to the subject's flight doctor within 5 days of data delivery to us.</p> <p><b>Other Activities:</b></p> <p>In FY2016 we added new study staff at the Center for Space Medicine, BCM. Kyla Cook joined the Center for Space Medicine and will serve as project manager and data analyst for the Dose Tracker project.</p> <p><b>Other Information &amp; Materials:</b></p> <ul style="list-style-type: none"> <li>• 1 abstract &amp; presentation at HRP IWS 2016:</li> <li>o V Wotring, K Cook, L Smith. Dose Tracker Application for Monitoring Crew Medication Usage, Symptoms, and Adverse Effects During Missions. NASA 2016 Human Research Program Investigators' Workshop. February 8-11, 2016. Galveston, TX, USA.</li> <li>o There have been no published articles in FY2016.</li> </ul> <p><b>References:</b></p> <p>Wotring, V. E. (2015). Medication use by U.S. crewmembers on the International Space Station. <i>Faseb j</i>, 29(11), 4417-4423. &lt;a target="_blank" href="http://dx.doi.org/10.1096/fj.14-264838"&gt;http://dx.doi.org/&lt;/a&gt;</p>

Bibliography Type:	Description: (Last Updated: 12/24/2019)