Fiscal Year:	FY 2016	**Task Last Updated:**	FY 11/30/2015
PI Name:	Wu, Lei Ph.D.		
Project Title:	Development of Predictive Degradation Models and Determination of Bioequivalence of Pharmaceutical Preparations Contained in the Medical Kits on Board the International Space Station (Postdoctoral Fellowship)		
Division Name:	Human Research		
Program/Discipline:			
Program/Discipline--Element/Subdiscipline:	NSBRI--Smart Medical Systems and Technology Team		
Joint Agency Name:		**TechPort:**	No
Human Research Program Elements:	(1) **ExMC**:Exploration Medical Capabilities		
Human Research Program Risks:	(1) **Stability**:Risk of Ineffective or Toxic Medications Due to Long Term Storage (IRP Rev F)		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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Zip Code:	77030	**Congressional District:**	9
Comments:			
Project Type:	GROUND	**Solicitation:**	2015 NSBRI-RFA-15-01 First Award Fellowships
Start Date:	10/01/2015	**End Date:**	10/01/2016
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:**	NSBRI
Contact Monitor:		**Contact Phone:**	
Contact Email:			
Flight Program:			
Flight Assignment:	NOTE: End date changed to 10/1/2016 to reflect actual end date of project (Ed., 4/12/17)		
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Chow, Diana Shu - Lian Ph.D. (MENTOR/ University of Houston) Nair, Ajith Ph.D. (Bilcare Research Inc.)		
Grant/Contract No.:	NCC 9-58-PF04306		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	POSTDOCTORAL FELLOWSHIP The environmental factors of space missions may cause accelerated physical-chemical degradation or alterations in the integrity of formulations stored on board space missions for extended periods such as on the International Space Station (ISS) and exploration missions. The degradation of the active pharmaceutical ingredient (API) and adjuvants in addition to alterations of the chemical matrix of the formulation can decrease potency and bioavailability, and increase the risk of toxicity of degraded medications. Therefore, characterizing degradation profiles and developing predictive models of degradation using results from ground-based accelerated stability, bioavailability, and toxicity studies is important to ensure safe and effective pharmacotherapeutics for astronauts during extended duration space missions. This research project addresses pharmacotherapeutics risks and gaps described in the Human Research Program (HRP) road map (ExMC 17, PHA 02), and related specific task of "Stability Analysis of ISS Medications." The overall goal of the proposed research is to develop and validate predictive degradation models for select pharmaceutical preparations contained in the ISS medical kits. A related objective of our research is to examine whether or not integrity and performance of degraded formulations is compromised as indicated by bioequivalence in ground-based animal model. The following specific aims will be pursued to accomplish our research goal: 1) Establish a validated HPLC-MS/MS assay method that can be used for the identification and quantification of API and degradation products of the selected formulations. 2) Characterize degradation profiles and API content of medications received from ISS and compare with existing data from ISS payload and irradiation studies. 3) Conduct ground-based accelerated stability studies with matching set of medications selected for the above aims to develop predictive degradation models. 4) Estimate bioequivalence between Earth-based control and Space X returned formulations in a small animal model (rat) to examine integrity and performance of medications stored on board the ISS.
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	
Task Progress:	New project for FY2016.
Bibliography Type:	Description: (Last Updated:)