Fiscal Year:	FY 2009	**Task Last Updated:**	FY 05/21/2009
PI Name:	LeBlanc, Adrian Ph.D.		
Project Title:	Bisphosphonates as a Countermeasure to Space Flight Induced Bone Loss: SMO-021		
Division Name:	Human Research		
Program/Discipline:	HUMAN RESEARCH		
Program/Discipline--Element/Subdiscipline:	HUMAN RESEARCH--Biomedical countermeasures		
Joint Agency Name:		**TechPort:**	Yes
Human Research Program Elements:	(1) **HHC**:Human Health Countermeasures		
Human Research Program Risks:	(1) **Bone Fracture**:Risk of Bone Fracture due to Spaceflight-induced Changes to Bone (2) **Osteo**:Risk Of Early Onset Osteoporosis Due To Spaceflight		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
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PI Organization Type:	NON-PROFIT	**Phone:**	281-244-2012
Organization Name:	Universities Space Research Association		
PI Address 1:	Division of Space Life Sciences		
PI Address 2:	3600 Bay Area Blvd		
PI Web Page:			
City:	Houston	**State:**	TX
Zip Code:	77058	**Congressional District:**	22
Comments:			
Project Type:	FLIGHT	**Solicitation / Funding Source:**	Directed Research
Start Date:	10/01/2006	**End Date:**	08/31/2015
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:	Goodwin, Thomas	**Contact Phone:**	
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Flight Program:	ISS		
Flight Assignment:	ISS NOTE: End date is 8/31/2015 per HRP Master Task List dtd 7/12/11 (Ed., 8/4/11) NOTE: Extended to 9/30/2013 per PI (11/5/2010)		
Key Personnel Changes/Previous PI:	Toshio Matsumoto, M.D., Ph.D., is the Japanese Co-Principal Investigator of this study, a joint project between NASA and JAXA. Dr. Matsumoto is affiliated with the Department of Medicine and Regulatory Sciences, University of Tokushima Graduate School of Medicine. His contact information is: Phone 81-88-633-7119/Fax 81-88-633-7407; Toshimat@clin.med.tokkushima-u.ac.jp.		
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Grant/Contract No.:	
Performance Goal No.:	
Performance Goal Text:	
Task Description:	The purpose of this Supplementary Medical Objective is to determine whether bisphosphonates, in conjunction with the routine in-flight exercise program, will protect ISS crewmembers from the regional decreases in bone mineral density documented on previous ISS flights. Two dosing regimens will be tested: (1) an oral dose of 70 mg alendronate taken weekly during flight and (2) and I.V. dose of zoledronic acid 4 mg, administered just once approximately 45 days before flight. Our rationale for including both alendronate and zoledronic acid is that two dosing options will: maximize crew participation, increase the countermeasure options available to flight surgeons, increase scientific opportunities, and minimize the effects of operational and logistical constraints. Use of both oral and I.V. options can accommodate both crew and flight surgeon preferences (e.g., based on individual drug sensitivity, relevant health conditions, or other considerations). Operational and logistical constraints may favor one option versus the other. For example, stowage limits may limit use of alendronate on certain flights, while the ability to titrate the in-flight dose in response to on-orbit measurements of bone resorption would favor the weekly dosing regimen. Long-duration (e.g., 2+ year) missions would require in-flight re-dosing of I.V. zoledronic acid. The purpose of this study is not to test one dosing option versus the other. Rather, we intend to show that bisphosphonates-plus-exercise will have a measurable effect versus exercise alone in preventing space flight induced bone loss. Secondary goals will be to document the return to normal bone remodeling post-flight in crewmembers who took bisphosphonates.
Rationale for HRP Directed Research:	
Research Impact/Earth Benefits:	While the primary purpose of this research is to develop a countermeasure to protect crewmembers against bone loss during long duration spaceflight, this research may provide insight into the mechanisms and prevention of bone atrophy in other disuse conditions.
Task Progress:	The first research subject/crewmember is currently in space aboard the ISS. This subject is taking a weekly oral dose of alendronate. All scheduled preflight and inflight measurments and data collection have occured according to plan. To date, the following activities have been accomplished: 1. Informed Consent Briefings;17 crewmembers. 2. Signed Consent Forms; 4 Prime and 2 Backup crew have currently volunteered to prticipate in this experiment. 3. Science Training; 8 crewmembers. 4. Urine and Pill Ingestion Training; 8 crewmembers. 5. Alendronate Tolerance Testing; 6 crewmembers. 6. Pre-Dosing Blood and Urine Collections (L-45); 6 crewmembers. 7. Post-Dosing Blood and Urine Collections (L-10); 1 crewmember. 8. Pre-Flight DXA; 2 crewmembers. 9. Pre-Flight pQCT; 2 crewmembers. 10. Pre-Flight High-Resolution QCT; 2 crewmembers. 11. Pre-Flight Renal Ultrasound; 2 crewmembers. 12. Pre-Flight Alendronate Dosing (L-17 to L-3); 2 crewmembers. 13. Pre-Flight Ca and Vit D supplementation; 2 crewmembers. 14. In-Flight Alendronate Dosing; 1 crewmember (in progress). 15. In-Flight Urine Collections; 1 crewmember (in progress).
Bibliography Type:	Description: (Last Updated: 06/29/2023)