YH 1 X7	EV. 2014		EX 05/21/2014
Fiscal Year:	FY 2014	Task Last Updated:	FY 05/31/2014
PI Name:	Urban, Randall M.D.		
Project Title:	Testosterone Supplementation as a C	ountermeasure against Musculoskeletal L	osses during Space Exploration
Division Name:	Human Research		
Program/Discipline:	HUMAN RESEARCH		
Program/Discipline Element/Subdiscipline:	HUMAN RESEARCHBiomedical	countermeasures	
Joint Agency Name:		TechPort:	Yes
Human Research Program Elements:	(1) HHC :Human Health Countermea	isures	
Human Research Program Risks:	(1) Muscle: Risk of Impaired Performance Due to Reduced Muscle Size, Strength and Endurance		
Space Biology Element:	None		
Space Biology Cross-Element Discipline:	None		
Space Biology Special Category:	None		
PI Email:	rurban@utmb.edu	Fax:	FY
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City:	Galveston	State:	TX
Zip Code:	77555-0569	Congressional District:	14
Comments:			
Project Type:	Ground	Solicitation / Funding Source:	2009 Crew Health NNJ09ZSA002N
Start Date:	07/30/2010	End Date:	07/29/2015
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:	NASA JSC
Contact Monitor:	Loerch, Linda	Contact Phone:	
Contact Email:	linda.loerch-1@nasa.gov		
Flight Program:			
Flight Assignment:	NOTE: Risk/Gap changes per IRP R NOTE: Extended to 7/29/2015, per N	ev E (Ed., 3/25/14) JSSC information and L. Loerch/JSC (Ed.	., 8/26/13)
Key Personnel Changes/Previous PI:			
COI Name (Institution):	Durham, William Ph.D. (University of Texas Medical Branch) Sheffield-Moore, Melinda Ph.D. (University of Texas Medical Branch) Dillon, Edgar Ph.D. (University of Texas Medical Branch)		
Grant/Contract No.:	NNX10AP86G		
Performance Goal No.:			
Performance Goal Text:			

Task Description:	The long-term goal of this proposal is to determine the therapeutic efficacy of testosterone at preserving lean muscle mass, muscle strength, and bone mineral density in healthy humans during spaceflight. We propose to examine the interactive or additive effects of the combination of testosterone and exercise on lean body mass (LBM), muscle strength, and bone health. Our general hypothesis is that the maintenance of normal physiologic levels of testosterone during spaceflight will protect against the functional loss of muscle and bone, and will maximize the efficacy of existing resistance exercise protocols at preventing or reversing functional impairments that occur during bed rest. To achieve these goals we will test the following specific hypotheses before, during, and after 70 days of bed rest:		
	1: Cycled testosterone replacement (weekly testosterone injections for 2 weeks, followed by 2 weeks off, etc.) in conjunction with exercise will have an additive effect in preventing loss of muscle mass and muscle strength in men representative of the astronaut population compared to exercise with placebo testosterone.		
	2: Cycled testosterone replacement (weekly testosterone injections for 2 weeks, followed by 2 weeks off, etc.) in conjunction with exercise will have an additive effect in preventing loss of bone mass and alterations in markers of bone metabolism in men representative of the astronaut population compared to exercise with placebo testosterone.		
	To address these hypotheses we will investigate the following specific aims before, during, and after 70 days of bed rest:		
	Aim 1: To determine the effect of cycled testosterone replacement in conjunction with resistance exercise during bed rest on muscle mass, muscle strength, and fatigue in men aged 24-55 years.		
	Aim 2: To determine the effect of cycled testosterone replacement in conjunction with resistance exercise during bed rest on markers of bone metabolism and bone mass in men aged 24-55 years.		
	Current evidence suggests that the combination of testosterone and exercise will optimize the effectiveness of the existing exercise and nutritional countermeasures. Results from this proposal will lay the ground work for the implementation of combinational countermeasures that will additively work to maintain preflight physiology of astronauts during long-term spaceflight missions.		
	Research Impact/Earth Benefits: Results from this study will further elucidate the role of testosterone in the maintenance of skeletal muscle and bone during long term bed rest as a model for spaceflight. The benefits to life on Earth are extensive.		
	It is hypothesized that maintaining appropriate balance between hormonal status, nutritional status, and physical activity during spaceflight is of critical importance in preventing musculoskeletal losses. It is our contention that the restoration of physiologic levels of testosterone is essential to prevent and/or restore spaceflight- and microgravity-induced losses in the musculoskeletal system. Current evidence suggests that the combination of testosterone and exercise will optimize the effectiveness of the existing exercise and nutritional countermeasures.		
Rationale for HRP Directed Research:			
Research Impact/Earth Benefits:	Results from this study will further elucidate the role of testosterone in the maintenance of skeletal muscle and bone during long term bed rest as a model for spaceflight. The benefits to life on Earth are extensive. It is hypothesized that maintaining appropriate balance between hormonal status, nutritional status, and physical activity during spaceflight is of critical importance in preventing musculoskeletal losses. It is our contention that the maintenance or restoration of physiologic levels of testosterone is essential to prevent and/or restore spaceflight- and microgravity-induced losses in the musculoskeletal system. Current evidence suggests that the combination of testosterone and exercise will optimize the effectiveness of the existing exercise and nutritional countermeasures.		
Task Progress:	 A total of 24 subjects successfully completed the protocol (8 non-exercising control, 8 exercising placebo-treated, and 8 exercising testosterone-treated subjects). Data were collected as planned.and final analyses are currently ongoing. 		
	3) Preliminary results have been presented in abstracts at meetings listed in the Bibliography section.		
	4) All data collected during this protocol will be comprehensively interpreted and the efficacy of the tested countermeasures on muscle strength, fatigue, and other outcome measures will be assessed.		
	5) Final results will be submitted for peer-review and publication.		
Bibliography Type:	Description: (Last Updated: 01/11/2021)		
Abstracts for Journals and Proceedings	 Dillon EL, Danesi CP, Randolph KM, Quisenberry JM, Gilkison CR, Durham WJ, Sheffield-Moore M, Urban RJ. "Testosterone Supplementation as a Countermeasure Against Musculoskeletal Losses During Space Exploration: CFT Preliminary Results." 2014 NASA Human Research Program Investigators' Workshop, Galveston, TX, February 12-1 2014. 2014 NASA Human Research Program Investigators' Workshop, Galveston, TX, February 12-13, 2014. 		
	http://www.hou.usra.edu/meetings/hrp2014/pdf/3157.pdf, Feb-2014		