Fiscal Year:	FY 2018	**Task Last Updated:**	FY 09/24/2018
PI Name:	Sibonga, Jean Ph.D.		
Project Title:	Astronaut Bone Medical Standards Derived from Finite Element [FE] Modeling of QCT Scans from Populations Studies		
Division Name:	Human Research		
Program/Discipline:	HUMAN RESEARCH		
Program/Discipline--Element/Subdiscipline:	HUMAN RESEARCH--Biomedical countermeasures		
Joint Agency Name:		**TechPort:**	No
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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Organization Name:	NASA Johnson Space Center		
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City:	Houston	**State:**	TX
Zip Code:	77058	**Congressional District:**	22
Comments:			
Project Type:	GROUND	**Solicitation / Funding Source:**	Directed Research
Start Date:	06/27/2012	**End Date:**	09/30/2018
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
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Flight Program:			
Flight Assignment:	NOTE: Project had been extended some time ago to 9/30/2018, per PI (Ed., 9/24/18) NOTE: Extended to 6/30/2016 per P. Baskin/HRP (Ed., 1/5/15) NOTE: Extended to 12/30/2014, per M. Covington/ JSC HRP (Ed., 7/3/14) NOTE: End date is 9/30/2014 per PI (Ed., 4/24/14) NOTE: Gap changes per IRP Rev E (Ed., 1/27/14)		
Key Personnel Changes/Previous PI:	September 2018 report: For the final year of the project, former CoInvestigators (CoIs) Sundeep Khosla, M.D. and Tony Keaveny, Ph.D. are no longer CoIs.		
COI Name (Institution):	Orwoll, Eric M.D. (Oregon Health and Sciences University) Amin, Shreyasee M.D. (Mayo Clinic) Lang, Thomas Ph.D. (University of California, San Francisco) Keyak, Joyce Ph.D. (University of California, Irvine) Cody, Dianna Ph.D. (University of Texas MD Anderson Center) Nicolella, Daniel Ph.D. (Southwest Research Institute) Cheung, Angela Ph.D., M.D. (University Health Network / Toronto Rehabilitation Institute / Mount Sinai Hospital)		

Grant/Contract No.:	Directed Research
Performance Goal No.:	
Performance Goal Text:	
Task Description:	A Research and Clinical Advisory Panel [RCAP] met in 2010 (Bone Summit) to review medical and research data of long-duration astronauts in order to make recommendations for the risk management for early onset osteoporosis in long duration astronauts. In its assessment, the RCAP stated that the guidelines using bone mineral density [BMD] T-scores as diagnostic criteria for osteoporosis have minimal clinical utility for the younger aged (< 50 years), predominantly male, astronaut cohort following exposure to prolonged spaceflight. In addition, NASA's research data have revealed that DXA measurement of hip BMD does not capture all of the effects of spaceflight that influence bone strength (Keyak et al., Bone 2009; 44(3):449-53). The Bone Summit RCAP recommended that NASA explore emerging population studies that use hip bone strength, as estimated from Finite Element [FE] models of QCT [quantitative computed tomography] scans, to supplement DXA bone mineral density [BMD] as a combined standard for bone health (Orwoll et al., J Bone Miner Res 2013; 28(6):1243-1255). To this aim, the Bone Discipline Lead (named as Principal Investigator), convened a Task Group of US principal investigators and FE modelers of those QCT population studies, along with one non-advocate FE modeler, to propose a FEM-based method by which bone medical standards could be modified. The FE strength cutoffs that are generated by this proposed method will be reviewed, modified if required, and accepted for recommendation by the FE Task Group as a bone health medical standard specific for astronauts exposed to the spaceflight environment. Specific Aims NASA's Bone medical standards establish the "operating bands for bone health" that: a) qualify an astronaut for long duration spaceflights, b) establish the non-permissible outcome for a spaceflight mission, c) provide a level of efficacy for countermeasures as well as d) screen for optimal bone health in an applicant for the astronaut corps. The current Bone medical standards are based upon the diagnostic criteria for a terrestrial population known to be at risk for osteoporosis, i.e., perimenopausal and postmenopausal women and men over the age of 50. As a follow-up to the Bone Summit RCAP recommendation, the FE Task Group proposes the following Specific Aims to accomplish the task of generating of FE-based medical standards to supplement the existing BMD T-score-based standards: 1) Develop a dataset of FE hip strengths from human subjects, with ages covering the age range of the astronauts and for which fracture outcome data have been collected. a. The Rochester Bone Health Study (as authorized by Drs. Sundeep Khosla and Shreyasee Amin) will provide QCT scans from ~408 persons to Dr. Joyce Keyak who will develop FE models and estimate hip bone strength using the FE modeling developed at University of Califormia Irvine (Keyak JH, et al. Clin Orthop Relat Res. 2005 Aug;(437):219-28). b. FE data from 1a (above) will be combined with FE data generated from other applications of Keyak FEM to QCT scans from additional study cohorts, which include International Space Station (ISS) astronauts. 2) Determine FE strength cutoffs, from Specific Aim 1b, to be used as a decision-tool by Space & Clinical Operations Division for the following scheduled decision points (a-d): a. to qualify a sub-set of applicants for astronaut candidacy (those who currently are not qualified due to hip T-score between -1 and -1.5) for further medical testing b. to qualify an astronaut for a long-duration (LD) mission c. to qualify a veteran LD astronaut for a second LD mission d. to establish responsibility by occupational space medicine for a post-mission fracture or osteoporosis diagnosis. 3) Present, review, and finalize the generated FE strength cutoffs with FE Task Group (along with the inclusion of cohort biostatisticians) to recommend to Human Health Countermeasures as a deliverable to the Space Medicine Space & Clinical Operations Division and Office of Chief Health and Medical Officer. (Ed. note: revised version, per PI. 8/27/2013)
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. Bone Medical standards provide the index by which the effects of spaceflight, the efficacy of countermeasures and the restoration of skeletal health following long-duration missions are all evaluated. Consequently, it is important and urgent to increase the sufficiency of our current bone medical standards in order not to risk underestimating the fracture or osteoporosis risks or the effectiveness and timing of strategies to mitigate the risk (e.g., in-flight countermeasures, selection criteria, flight certification). The Bone Summit RCAP of 2010, which made the recommendation to modify the BMD-based bone medical standards to be more relevant to the target population (i.e., long-duraiton astronauts), was composed of leaders in the International Society of Clinical Densitometry [ISCD] – This society formulates the positions by which BMD is used in clinical practice in terrestrial medicine and currently by the JSC Bone and Mineral Laboratory for Med Volume b and for required astronaut medical evaluation.
Research Impact/Earth Benefits:	A successful demonstration will demonstrate how Finite Element Models could enhance the ability to determine fracture probability in terrestrial populations.

Task Progress:	Experiment Status Specific Aims 1) Develop a dataset of FE hip strengths for subjects a) with ages covering the age range of the astronauts, and b) for which fractures outcome data have been collected. Completed. 12/03/13. 2) Review and evaluate dataset by FE Task Group members to suggest method(s) by which FE strength cutoffs from this dataset could be to supplement current areal BMD-based standards for the following: a) a non-permissible outcome (POL) for hip bone strength after spaceflight to establish level of countermeasure efficacy, b) an additional metric for screening bone health in applicants to the astronaut corps who fail to meet the bone medical standard of hip T-score>-1.0, c) a fitness-for-flight standard in astronauts for a second long-duration mission, and d) an index for assessing an astronaut's risk for overloading the hip due to certain post-mission physical activities. 3) A manuscript of FE Task Group opinions (#2 above) will be prepared for concurrence by Task Group members and submitted for publication. Hip "Load Capacity" as Cut-points for Astronaut Skeletal Health: Recommendations of the NASA Finite Element (FE) Strength Task Group. Andrew S. Michalski , Shreyasee Amin MD , Angela M. Cheung MD , Dianna D. Cody PhD , Joyce H. Keyak PhD , Thomas F. Lang PhD , Daniel P. Nicolella PhD , Eric S. Orwoll MD , Steven K. Boyd PhD , Jean D. Sibonga PhD. Completed. 9/30/18 and manuscript awaiting approval for submission to npgMicrogravity.
Bibliography Type:	Description: (Last Updated: 05/24/2021)
Abstracts for Journals and Proceedings	Michalski AS, Feiveson AH, Lewandowski B, Amin S, Keyak J, Boyd SK, Sibonga JD. "A spaceflight bone deconditioning model for predicting mission-specific fracture risk." Canadian Orthopaedic Research Society Annual Meeting 2018, Victoria, BC, Canada, June 21, 2018. Canadian Orthopaedic Research Society Annual Meeting 2018, Victoria, BC, Canada, June 21, 2018. , Jun-2018
Abstracts for Journals and Proceedings	Michalski AS, Amin S, Keyak J, Lewandowski B, Boyd SK, Sibonga JD. "Long-duration astronaut QCT-FE as a biomechanical approach for probabilistic fracture risk assessment." Canadian Aeronautics and Space Institute 18th Astronautics Conference, Quebec City, QC, Canada, May 15-17, 2018. Canadian Aeronautics and Space Institute 18th Astronautics Conference, Quebec City, QC, Canada, May 15-17, 2018. , May-2018
Articles in Peer-reviewed Journals	Michalski AS, Amin S, Cheung AM, Cody DD, Keyak JH, Lang TF, Nicolella DP, Orwoll ES, Boyd SK, Sibonga JD. "Hip load capacity cut-points for Astronaut Skeletal Health NASA Finite Element Strength Task Group Recommendations." npgMicrogravity. 2019 Mar;5(1):6. https://doi.org/10.1038/s41526-019-0066-3 ; PubMed PMID: 30886891; PubMed Central PMCID: PMC6418107 , Mar-2019
NASA Technical Documents	Sibonga JD, Truszkowski P. "Conference Proceedings -2010 Bone Summit: Risk for Early Onset Osteoporosis." Houston, TX: NASA Johnson Space Center, 2016. 40 p. NASA/TM-2016-219284. , Dec-2016