

12th Meeting of the US/Russian Joint Working Group on Space Biomedical and Biological Sciences Research Moscow, Russia

JUNE 4, 2009

NASA

HUMAN RESEARCH PROGRAM (HRP)

**INTERNATIONAL SPACE STATION MEDICAL PROJECT
(ISSMP)**

**Clarence F. Sams, Ph.D.
ISSMP Project Scientist**

STABILITY

Stability of Pharmacotherapeutic and Nutritional Compounds Lakshmi Putcha Ph.D. and Scott M. Smith, Ph.D.

Description: Analysis of returned foods and drugs from ISS has indicated that some pharmaceuticals and vitamins are significantly degraded in space, and this may harm the health of crews on future exploration missions. Stability will identify those pharmaceuticals, vitamins, and amino acids that degrade in space and collect controlled data on the timecourse of degradation of in space. The data gathered from Stability will support the development of mathematical models to predict shelf life of products for long duration exploration missions and be the foundation for future efforts for alternative formulation, packaging and shielding for medicines and foods to ensure the integrity and quality of products used by crew during exploration missions.



BDC: Identical kits stored on the ground as controls

On-Orbit Ops: Four identical sample kits (containing pharmaceuticals, food, dosimeter and a temperature sensor) were delivered to ISS during the STS-121 mission, July, 2006. The final kit was returned on STS-126 in November 2008 after 29 months in a microgravity environment and sample analysis is in progress.

PFE-OUM

Periodic Fitness Evaluation with Oxygen Uptake Measurement

Sean K. Roden M.D., JSC and Filippo Castrucci, M.D., ESA

Description: The PFE-OUM was a collaborative effort between NASA and ESA for the evaluation of crew aerobic capacity. The Pulmonary Function System upgraded hardware provided the ability to directly measure oxygen consumption with the crew breathing through a mouthpiece in the performance of the routine PFE evaluation.

Subjects Required: 7 ISS crewmembers

BDC:

Preflight, subjects will undergo a peak cycle test and a submaximal cycle test . Postflight, the subjects will perform the nominal submaximal cycle test at R+5/7 and R+30 days.

On-Orbit Ops: In-flight, subjects will setup and calibrate the PFE-OUM hardware and perform the exercise protocol on the CEVIS. Blood pressure and ECG were measured throughout the protocol continuously. The initial in-flight PFE-OUM session was performed at flight day 14 and then every 30 days after throughout the mission.



NUTRITION

Nutritional Status Assessment

Scott M. Smith, Ph.D.

Description: Assessment of space flight impact on crew nutritional status, bone health, and rehabilitation. The data collected will allow for the evaluation of the efficacy of current and potential countermeasures.

Subjects Required: 12 Long

BDC: Void-by-void 48 hour urine samples, fasting blood samples, a sublingual swab for tissue mineral testing, and exercise logs will be collected two times preflight and two times postflight . An additional blood draw at L-10 will also be performed and two DEXA scans (one preflight and one postflight) will be obtained.

On-Orbit Ops: Blood and void-by-void 24 hour urine samples are collected five times in-flight (at FD15, 30, 60, 120, and 180). In-flight body mass, dietary and exercise data are obtained from Space Medicine.



Cardiovascular and Cerebrovascular Control on Return from ISS

Richard Hughson, Ph.D./University of Waterloo, Canada

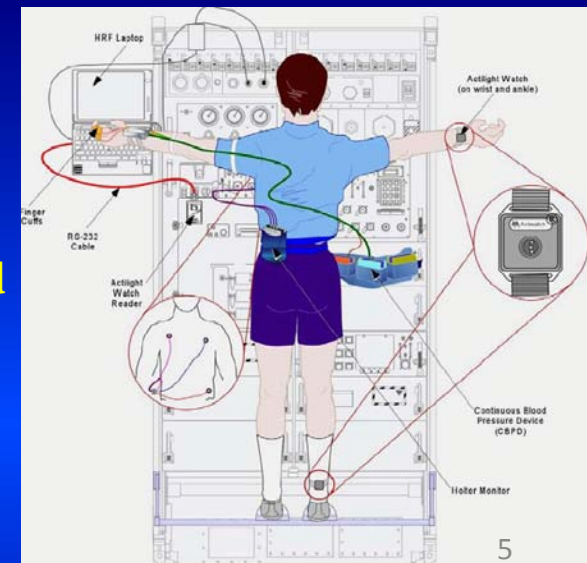
Description: Perform tests to characterize in-flight changes in cardiovascular and cerebrovascular function that might preclude crewmembers from being able to overcome postflight orthostatic intolerance.

Subjects Required: 6 ISS crewmembers

BDC: Recordings of heart rate and arterial blood pressure during 5-minutes of quiet, resting conditions and during 5-minutes of timed breathing. 24-hour recordings of heart rate and physical activity at L-30 and one session between R+1 & R+5

Lower Body Negative Pressure (LBNP) Protocol at L-30 within 24 hours, ideally prior to subject assuming upright position

On-Orbit Ops: One session early (between FD14 and 21) and one session late in the increment.



SLEEP

Sleep-Wake Actigraphy & Light Exposure during Space Flight

Charles Czeisler, Ph.D., M.D.

Description: The success & effectiveness of manned spaceflight depends on the ability of crewmembers to maintain a high level of cognitive performance & vigilance. Astronauts, however, commonly experience sleep disruption & may experience misalignment of circadian phase during spaceflight. Both of these conditions are associated with insomnia, &and impairment of alertness & cognitive performance.



Subjects Required: 20 Long, All Shuttle

BDC: Actiwatch recording, daily sleep logs, and a debrief will be performed preflight and postflight.

On-Orbit Ops: Crewmembers will don Actiwatches as soon as possible after launch and wear the watches continuously throughout the mission. Crewmembers will complete an electronic Sleep log for 7 consecutive days during at least three weeks on-orbit.

BRASLET

Validation of On-Orbit Methodology for the Assessment of Cardiac Function and Changes in the Circulating Volume Using Ultrasound and Braslet-M Occlusion Cuffs

J. Michael Duncan, M.D., JSC and Valery Bogomolov, M.D. Ph.D., IBMP

Description: Evaluation of ultrasound methodology for the measurement of cardiovascular volume and function in microgravity. This study combines the use of Braslet-M devices as a means to acutely alter volume distribution while focused ultrasound measurement techniques are developed. The successful development of this measurement technique will provide a means of measuring cardiovascular function, methodologies that will result in significant new capability and knowledge enhancing areas of operational space medicine including clinical management of volume shifts induced by altered gravity, clinical diagnostic ultrasound in space flight, and telemedicine.

Subjects Required: 5 ISS crewmembers, 10 paired scans

BDC: No preflight activities

On-Orbit Ops: Two in-flight sessions per crewmember



INTEGRATED IMMUNE

Validation of Procedures for Monitoring Crewmember Immune Function

Clarence Sams, Ph.D

Description: Immune dysregulation has been demonstrated to occur during spaceflight, This investigation assesses the clinical risks resulting from the adverse effects of spaceflight on the human immune system and will validate a flight-compatible immune monitoring strategy.

Subjects Required: 17 ISS and 17 Shuttle crewmembers

BDC: Short-duration crewmembers provide blood, urine, and saliva samples (both liquid and dry book) at L-180, L-10, R+0, and R+14. Long-duration crewmembers provide the same samples at L-180, L-45, R+0, and R+30.

On-Orbit Ops: Short-duration crewmembers take liquid saliva samples every other day throughout the flight and dry book saliva samples on FD2 and R-1. A blood sample is also required the day before landing. Long-duration crewmembers provide four liquid saliva samples (collected every other day), one dry book saliva sample, and one blood sample at three points during their mission (early, middle, and late increment).



EPSTEIN-BARR

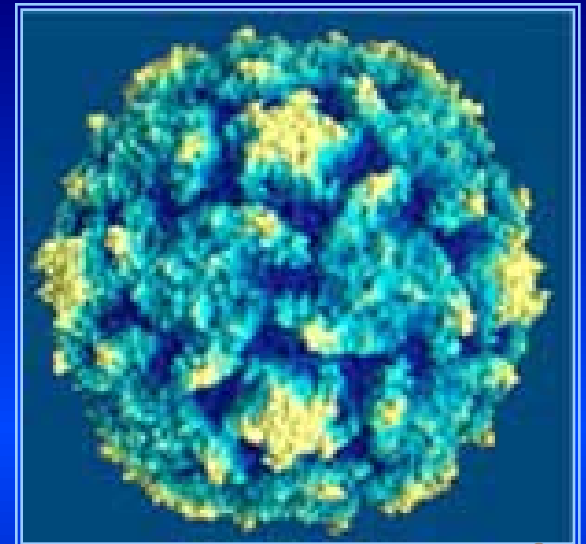
Space Flight-Induced Reactivation of Latent Epstein-Barr Virus Raymond Stowe, Ph.D.

Description: As spaceflight mission duration increases, the potential development of infectious illness in crewmembers during flight also increases. This is especially true with latent viruses and infections caused by these viruses are not mitigated by a quarantine period. An example of a latent infection is Epstein-Barr virus (EBV), of which approximately 90% of the adult population is infected. Stress and other acute/chronic events reactivate this virus from latency, which results in increased viral replication. This investigation will assess the immune system function using blood and urine samples collected before and after spaceflight.

Subjects Required: 17 ISS crewmembers

BDC: Blood and 24-hour urine samples will be collected preflight (L-180, L-44, L-10 and L-3 or 2 days) and after landing (R+0, R+3, R+14 and R+180).

On-Orbit Ops: None



JOURNALS

Behavioral Issues Associated with Isolation and Confinement

Jack Stuster, Ph.D., Anacapa Sciences, Incorporated, Santa Barbara, CA

Description: Isolation and confinement on long duration space missions can impact crew health and morale which are important factors that can affect mission success. This study converts behavioral and human factors data contained in journal entries into quantitative data on the importance of different behavioral issues in long duration crews. By studying what crewmembers write about, it is hoped that we can identify those things that are most important to long duration crews. Findings will help sustain human performance during long duration space missions.

Subjects Required: 10 ISS crewmembers

On-Orbit Ops: Crewmembers complete a journal (electronic or paper) with their thoughts and experiences for 15 minutes at least three times a week. Also completed prior to launch, midway through the increment and several days following return to Earth.

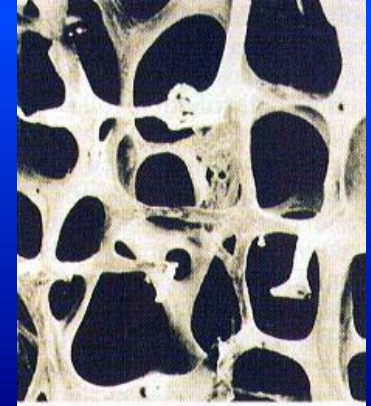


BISPHOSPHONATES

Bisphosphonates as a Countermeasure to Space Flight Induced Bone Loss

Adrian LeBlanc, Ph.D. and Toshio Matsumoto, M.D., Ph.D.

Description: Evaluation of bisphosphonates (either oral alendronate taken weekly throughout flight or IV zoledronic acid administered once preflight), 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.



Subjects Required: 10 Long (5 alendronate, 5 zoledronic acid)

BDC: Preflight all subjects will complete DXA scans, peripheral (limb) QCT Scans , high resolution QCT scans, blood draws with 24-hr urine collections, and ultrasound imaging for assessment of renal stones. Alendronate subjects will begin ingestion on L-17, L-10, & L-3. Zoledronic Acid subjects will be administered the bisphosphonate on L-45 . At L-90, baseline health status will be obtained for all subjects prior to preflight dosing with bisphosphonates. All subjects will begin Vitamin D and calcium supplementation as early as L-75.

On-Orbit Ops: Alendronate subjects will ingest a pill weekly and all subjects will take daily Vitamin D supplements. Three 24 hr urine collection sessions (early, mid, and late-increment) will be performed by each subject . Diet and exercise logs will be obtained via data sharing.

REPOSITORY

NASA Biological Specimen Repository Kathleen McMonigal, M.D.

Description: Biological specimens provide a means for investigating the physiological responses to spaceflight. Blood and urine are collected before, during and after long-duration flight in order to establish an archive of human biological samples. This archive, which will include samples from many different flights, will provide a potential population for future research activities and will serve as a valuable resource with which future investigators can validate clinical hypotheses, study spaceflight-related physiological changes, and investigate physiological markers.



Subjects Required: All USOS ISS crewmembers

BDC: Blood draw and 24 hr urine collection at L-45, R+3/7 and R+30

On-Orbit Ops: Blood draw (two tubes) and 24 hr void-by-void urine collection (one sample each void) at FD15, 30, 60, 120, and 180

INTEGRATED CARDIOVASCULAR

Cardiac Atrophy and Diastolic Dysfunction During and After Long Duration Spaceflight

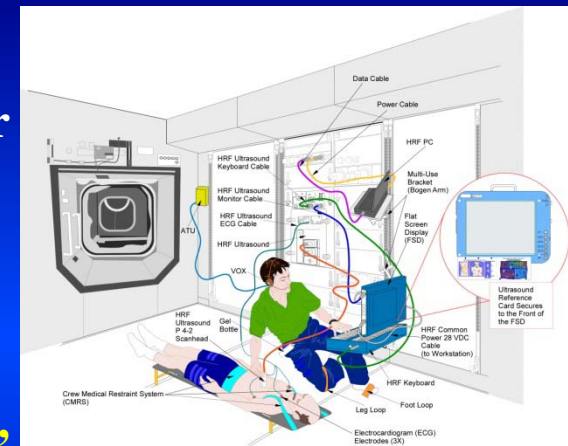
Benjamin D. Levine, M.D. and Michael W. Bungo, M.D.

Description: Determine the magnitude of left and right Ventricular atrophy associated with long-duration spaceflight, and relate this atrophy to measures of physical activity and cardiac work in-flight. Determine the time course and pattern of progression of cardiac atrophy in-flight using cardiac ultrasound, determine the functional importance of cardiac atrophy for cardiac diastolic function and the regulation of stroke volume during gravitational transitions, and identify changes in ventricular conduction, depolarization and repolarization during and after long-duration spaceflight and relate these to changes in cardiac mass and morphology.

Subjects Required: 12 Long

BDC: Resting and Exercise Echocardiograms with ECG, 48-hr BP/Holter/Activity Monitoring, Cardiac Function Test, MRI

On-Orbit Ops: Resting Echo and Exercise Echo with 24-hr BP/Holter/Activity Monitoring



VO₂max

Evaluation of Maximal Oxygen Uptake and Submaximal Estimates of VO₂max Before, During, and After Long Duration International Space Station Missions

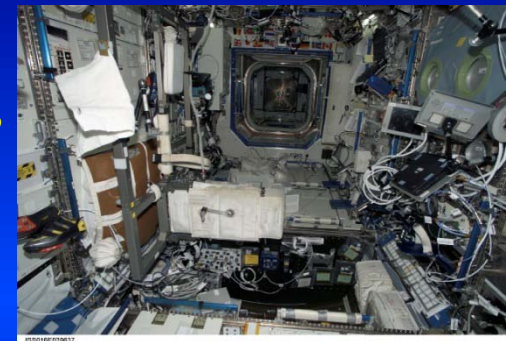
Alan D. Moore, Jr., Ph.D., Johnson Space Center, Houston, TX

Description: VO₂max is the standard measure of aerobic capacity and is directly related to the physical working capacity of an individual. VO₂max is related to the ability to perform an egress task while wearing a Launch and Escape space suit; therefore, decreased VO₂max may represent a safety concern in the event of an emergency during space flight. This investigation will measure the aerobic capacities of the crewmembers onboard the ISS. By understanding the changes in VO₂max that occur within space flight, necessary adjustments can be made to EVA exercise countermeasures.

Subjects Required: 12 ISS crewmembers

BDC: VO₂max protocol at L-270, -60, -30, R+1, +10 and +30. Measures heart rate, blood pressure, volume of oxygen utilized, volume of carbon dioxide produced, cardiac output, workload and perception of effort.

On-Orbit Ops: VO₂max protocol at FD15 and every 30 days



Current NASA Human Research Program Flight Investigations

Investigation	Subjects		Status (through Increment 18)
	Required	Completed	
Stability	4 kits	4 kits	Flight activities completed, final kit returned, sample and data analysis in progress
PFE-OUM	7	7	All operations completed, data analysis in progress
Nutrition	24	8	Crewmembers participating during Increment 19, Flight samples returned from Increment 16-18 and analysis in progress
CCISS	6	4	Crewmembers participating during Increment 19, planned completion of study expected after Increment 20/21
Sleep	All Shuttle 20 ISS	47 Shuttle 7 ISS	Study has successfully recruited ISS crewmembers for Increments 18-21
Braslet	10 scans	11	Investigation currently in progress during Increment 18
Integrated Immune	17 Shuttle 17 ISS	10 Shuttle 7 ISS	Study has successfully recruited ISS crewmembers for Increments 19-21, Shuttle phase of study expected to be completed in 2009
Epstein Barr	41 Shuttle 17 ISS	36 Shuttle 18 ISS	Investigation is scheduled to fly its final subjects on both Shuttle and ISS missions in early 2009

Current NASA Human Research Program Flight Investigations

Ops Title	Subjects		Status (through Increment 18)
	Required	Completed	
Journals	10	11	Study completed following Increment 18 postflight activities
Bisphosphonate	10	0	Initial in-flight operations for this study scheduled to start during Increment 19
Repository	All	7	Repository operations began with Increment 16 Recruitment continues for all future ISS missions
Harness	5	0	New hardware has completed flight certification, initial in-flight operations are scheduled to begin with Increment 19
Spinal	23	0	Three crewmembers successfully recruited for participation during the STS-128 mission scheduled for August 2009
ICV	12	0	Successfully recruited the first three subjects for this investigation, flight operations are scheduled to begin with Increment 19

FUTURE FLIGHT INVESTIGATIONS

Physiological Factors Contributing to Post-flight Changes in Functional Performance (FTT)

PI: Jacob Bloomberg, Ph.D.

An integrated set of functional and physiological tests to determine how postflight changes in sensorimotor, cardiovascular, and muscle physiology impact functional performance.



Development of a New Instrumented Harness For Use In Spaceflight Exercise Countermeasures (Harness)

PI; Gail Perusek



Evaluation of a new treadmill harness design for comfort during exercise, and measurement of the loads in the harness straps for direct comparison with the current U.S. TVIS Harness. The research protocol is aimed at improving comfort, plus increasing consistent loading for crewmembers exercising on the ISS treadmill.

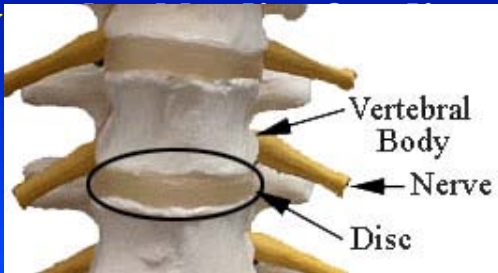
Psychomotor Vigilance Test (Reaction Self Test)

PI: David Dinges, Ph.D.

The PVT Self Test provides astronauts with objective feedback on neurobehavioral changes in vigilant attention, psychomotor speed, state stability, and impulsivity. It will evaluate the extent to which PVT Self Test performance of astronauts is sensitive to fatigue from sleep loss and circadian disruption during the mission, fatigue from work intensity during the mission, decline of performance with time during the mission, and carry-over effects of medications for sleep on ISS.

Vertebral Compression Fracture NASA Space Medicine

The study will collect data for the measurement of morphological changes to vertebral bodies and analysis of asymptomatic compression fractures in crewmembers after long-duration spaceflight and to evaluate morphological changes to vertebral bodies with longitudinal measures in the astronaut population to characterize changes over time.



Dietary Intake Can Predict and Protect Against Changes In Bone Metabolism During Space Flight And Recovery (Pro-K) **PI: Scott Smith, Ph.D.**

This investigation will study the role of dietary intake patterns as one of the factors associated with bone mineral loss in space flight. The protocol is designed to study the role of acid and base precursors in the diet.



This protocol will test the hypothesis that the ratio of acid precursors to base precursors (specifically animal protein and potassium, respectively) in the diet can predict changes in the loss of bone mineral during space flight and recovery.



Human Factors Assessment of Vibration Effects on Visual Performance (Visual Performance) **PI: Katrina Holden, Ph.D.**

Investigation to determine visual performance limits during operational vibration and g-loads on the Space Shuttle, specifically through the determination of minimum readable font size during ascent using planned Orion display formats.

Urine Monitoring System (UMS)

PI: Daniel Feedback, Ph.D.

The ISS Urine Monitoring System is an automated void volume measurement and sample acquisition system for long term ISS science application. The UMS is capable of collecting and accurately measuring void volume , separating urine from air and allowing acquisition of individual, uncontaminated urine samples. Scheduled to launch on STS-130 (Feb, 2010)



Integrated Resistance and Aerobic Training Study (IRAT)

PI: Lori Ploutz-Snyder, Ph.D.

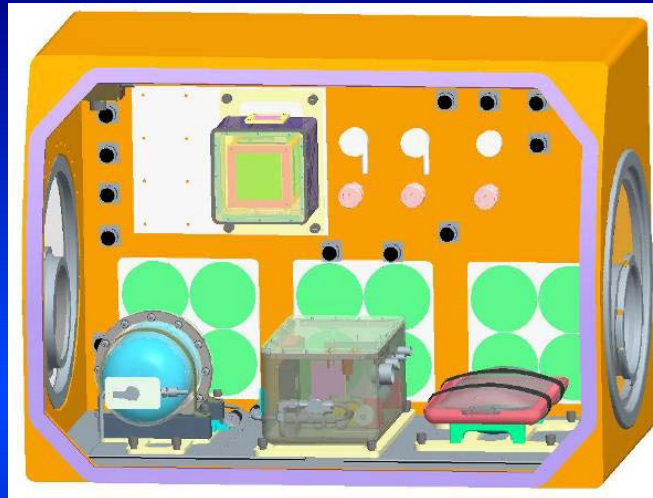
Evaluation of the efficacy of a new integrated resistance and aerobic training (iRAT) program designed to minimize loss of muscle, bone and cardiovascular function using the ISS exercise hardware including the second generation treadmill and the ARED device. Highlights of the iRAT include an increase in the intensity and a reduction in the volume of resistance exercises, inclusion of very short, but high intensity interval-type aerobic exercises, and starting the exercise countermeasures as early as possible in the flight, preferably in the first week.



Intravenous Fluids Generation for Exploration Missions (IVGEN)

PI: John McQuillen

IVGEN is a hardware technology development and demonstration effort to demonstrate the capability to purify water to the standards required for IV administration, then mix the water with salt crystals to produce normal saline. This hardware is a prototype that will allow flight surgeons more options to treat ill or injured crew members both onboard ISS and during exploration missions.



Spinal Elongation and its Effects on Seated Height in a Microgravity Environment

PI: Sadhaker Rajulu, Ph.D.

Collection of spinal elongation induced seated and standing height data in crewmembers and provide information relating to the seated height rate of change over time for astronauts subjected to microgravity. This seated height data in microgravity is considered necessary to correctly identify the seated height projections of the crew in the Orion configuration allowing for proper positioning of the seats within the vehicle, maintaining adequate clearance for seat stroke in high acceleration impacts, providing proper fit in seats, proper placement of seats with respect to each other and the vehicle; and proper orientation to displays and controls. Additionally, data concerning the effects of spinal elongation on seated height would aid in the design of suit components, habitation requirements and tool specifications.





NASA-ISSMP



- **Provide planning, integration, and implementation services for Human Research Program research tasks**
- **Maximize the utilization the ISS to assess the effects of long-duration spaceflight on human systems**
- **Define science protocols as set of implementable functional requirements to design operational scenarios**
- **Develop & certify hardware/software**

NASA-ISSMP

- **Develop & validate crew procedures and provide crew training**
- **Monitor real-time ops and facilitate data transfer & remote PI interface**
- **Coordinate BDC schedules to facilitate pre-and post flight data collections with International Partners**

