Acceleration Measurements in Reduced Gravity

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Abstract

Acceleration Measurements in Reduced Gravity

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Mitigation of bone loss as a result of long-duration exposure to microgravity is a serious medical concern for astronauts. With stays on the International Space Station (ISS) spanning from 6 months to a year, crew members are returning to Earth with a skeleton whose structural integrity has been significantly compromised, placing them at risk for bone fracture upon re-exposure to a gravitational environment.

Mechanical stimulus delivered to the lower extremity is beneficial to the development, growth or repair of bone. In order to monitor and quantify the mechanical stimulus delivered to the lower extremity during bouts of physical activity such as exercise an accelerometer-based activity monitoring system was developed and tested in a variety of real and simulated gravity environments.

The activity monitoring system has been demonstrated in an operational and flight-like setting to successfully record accelerations during exercise in microgravity. Acceleration and force data were collected and analyzed in various gravity conditions to reveal a positive and significant relationship between accelerations recorded at the hip and vertical ground reaction forces. This will enable future exercise prescriptions to be developed and evaluated. The small

package size, wireless Bluetooth capability and the ability to be unobtrusively worn during exercise or activities of daily living make the activity monitoring system appealing not only for use in space exploration, but also for use on Earth.

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Chapter 1. INTRODUCTION

Osteoporosis is a disease that causes bones to become weak and brittle due to a marked loss of bone mineral density. Osteoporosis affects approximately 10 million Americans and is becoming an increasing health risk to our aging population. Osteoporosis is primarily known only as a risk to older women. While older women are an at-risk population, men are also at risk: as many as 50% of women and 25% of men older than 50 will fracture a bone due to osteoporosis. Aside from hospitalization and limited mobility as a result of hip fracture, the risks extend much further: the U.S. Department of Health and Human Services found that 1 in every 5 hip fracture patients die within a year of their injury [19]. According to a study on the incidence and economic burden of osteoporosis-related fractures, more than 2 million osteoporosis-related fractures were treated in 2005, with total medical costs of approximately $17 billion. By 2025, those numbers are expected to grow to more than 3 million fractures and $25.3 billion in costs [4]. In order to reduce the incidence of osteoporosis-related fractures and medical expenses associated with the osteoporosis, it is critical to develop preventative strategies to mitigate the rapidly growing burden of this disease.

In addition to aging citizens, another population at risk for loss of bone mineral density (BMD) is astronauts living and working in space. In order to ensure safe, reliable, and productive human space exploration, it is necessary to address these medical challenges facing astronauts and implement preventative measures. One of the top medical priorities for the National Aeronautics and Space Administration (NASA) is the mitigation of bone loss as a result of long-duration exposure to microgravity. Pre- and post-flight assessments have shown that astronauts lose approximately 1-2% of regional bone mass for each month spent in low-earth orbit in spite of present exercise countermeasures [15]. This amount of bone loss per month is equivalent to what an older, osteoporotic woman on Earth experiences in an entire year [20]. With stays on the International Space Station (ISS) spanning from 6 months to a year, crew members are returning to Earth with a skeleton whose structural integrity has been significantly compromised, placing them at risk for bone fracture upon re-exposure to a gravitational environment [21].

Presently, bone loss countermeasures in low-earth orbit include nutritional plans and physical exercise consisting of resistive and aerobic activities; however, the effects of these countermeasures remain unclear. On Earth, it has been shown that mechanical stimulus delivered to the lower extremity has osteogenic effects on the skeleton (i.e. beneficial to the development, growth or repair of bone). This is of particular importance in weight-bearing bones including the femur, pelvis, and lumbar region of the spine, which are susceptible to fracture when BMD is compromised [1]. Unfortunately, crews presently aboard the International Space Station are unable to monitor the forces applied to the body as a result of exercise. This makes it difficult to predict if crew members are meeting their daily bone health requirements. If the mechanical stimulus delivered to crew members during bouts of physical exercise could be monitored and quantified, an estimation of osteogenic activity could be made.

In order to monitor and quantify the mechanical stimulus delivered to the lower extremity during bouts of physical activity such as exercise, an activity monitoring system was developed as a result of the National Space Biomedical Research Institute (NSBRI) study “Monitoring Bone Health by Daily Load Stimulus Measurement During Lunar Spaceflights” by ZIN Technologies (Cleveland, Ohio). The activity monitoring system is an accelerometer-based system featuring sensors that would be worn by crew members during exercise to unobtrusively monitor the accelerations they experience and interpret that data in relation to bone health. The long-term objective of this research is to utilize the activity monitoring system to alert crew members aboard the ISS or on long-duration spaceflight missions whether or not they have reached their daily quota of physical activity for bone health maintenance. Beyond the direct application to long-duration crew members, this research may also benefit medical patients, athletes and the general aging population.

Chapter 2. LITERATURE REVIEW

2.1 BONE FUNCTION, STRUCTURE AND STRENGTH

Bone is a type of dense, living connective tissue that constitutes the human skeleton and serves three important functions:

(1) Mechanical: provides the structural means to support against gravitational forces and applied loads and enables locomotion by serving as the lever arms and attachment sites for muscles;
(2) Protective: protects vital organs and bone marrow;
(3) Physiological: produces red and white blood cells and stores minerals.

Two types of osseous tissue constitute bone: cortical and trabecular. About 80% of the total skeleton is composed of cortical, or compact, bone: the thick, dense external layer of calcified tissue. Trabecular, or cancellous, tissue forms the inner portion of bone. Trabecular bone is primarily found at the end of long bones, proximal to joints, where it gives supporting strength to weight-bearing bones such as the femur, pelvis or vertebrae [14]. As seen in Figure 1, trabecular bone is spongy and less dense than cortical bone (30 - 90% porosity, versus < 30% porosity in cortical) and plays an important role in the vascular system as it is the location for blood cell production [26].

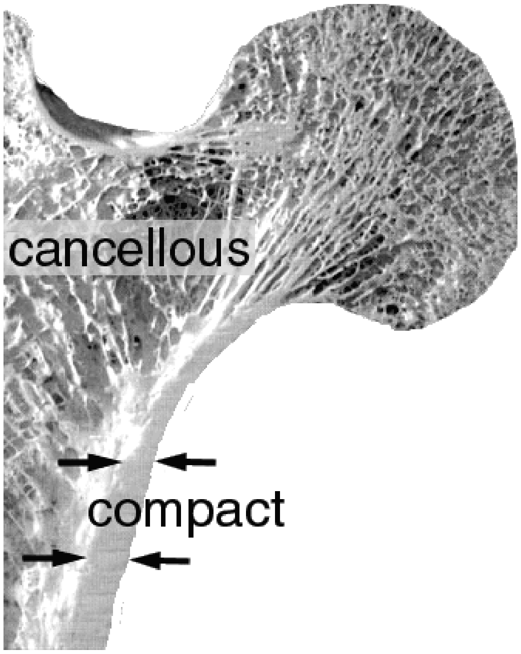


Figure 1 Cross-section of the femur showing cancellous (trabecular) and compact (cortical) bone *[2]*

The name for trabecular bone is derived from the Latin word *trabecula*, meaning “little beam”. The name is very fitting for this osseous tissue as the individual elements of trabecular bone form a three-dimensional network of small, beam-like structures which are specifically oriented to make bone stronger in the direction of maximum load. This directional distribution, or anisotropy, of trabeculae is illustrated in the proximal femur in Figure 2. Bone is strongest in compression, aiding in resistance to compressive stress as a result of body weight. Bone is also capable of resisting forces due to tensile loads such as those applied from muscle. The ability to resist compressive and tensile forces is a result of bone’s material properties. Bone is a composite material composed of mineral embedded in a matrix of collagen [23]. Both of these provide strength and resilience in order for bone to absorb impact [17]. Mineral, which makes up approximately 65% of bone, gives bone its ability to resist deformation, or stiffness. Collagen, on the other hand, has a low elastic modulus, with high tensile strength enabling bone to flex and resist tension. This is significant in areas of bone which are experiencing a moment and thus being placed in tension, such as the femoral neck. Collagen is progressively lost with age, increasing susceptibility to tensile loads and placing the elderly population at risk for fractures these regions.

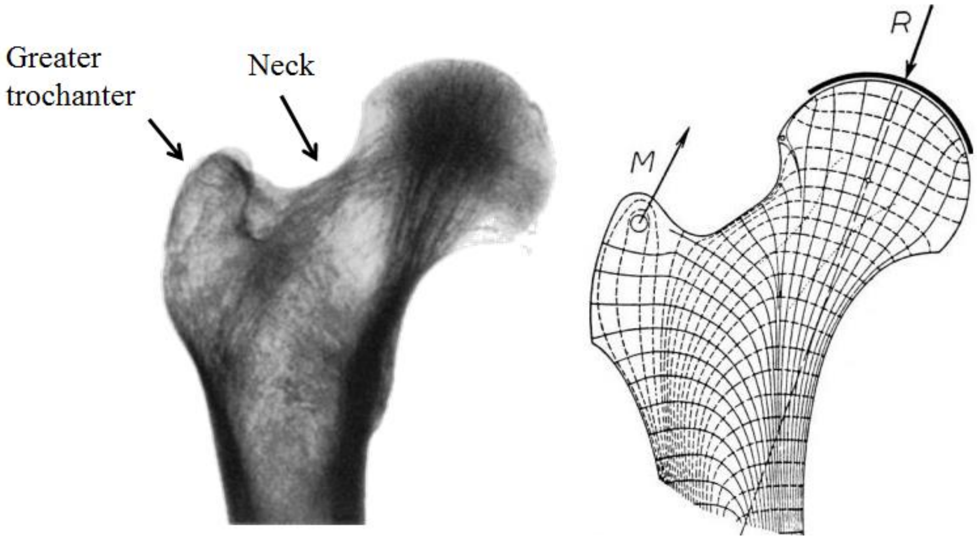


Figure 2 X-ray image of the trabecular architecture (left) and the anisotropy of stress distribution (right) of the proximal femur. Image adapted from *[27]*.

2.2 BONE ADAPTATION TO MECHANICAL LOADING

For over 100 years, bone adaptation due to mechanical loading has been acknowledged. In 1892, Wolff's paper, *The Law of Bone Transformation* suggests that the architecture of bone follows its function. Specifically, Wolff's law states that bone in a healthy person will adapt to the loads under which it is placed and that, if loading of a bone increases, the bone will remodel itself to become stronger in order to resist similar loading stresses in the future. A common example exhibiting this phenomenon is in tennis players: the bone cortex size is larger for their dominant playing arm than that of their non-dominant arm [10].

In 1917, Thompson elaborated on Wolff's observations stating that, "Strain, the result of stress, is a direct stimulus to growth itself". Thompson also suggested that the shear stress produced as a result of bone deformation may play a significant role in the mechanical signaling process of bone adaptation. Building upon this, Harold Frost developed the Mechanostat, a model describing bone growth and loss as a result of local, mechanical elastic deformation of bone. During nominal operation, bone's control loop senses strain and maintains bone mass; if the strain within a bone exceeds a set point, modeling of the bone occurs to reduce the strain back to the initial set point.

Frost identified four regions of strain which impact bone adaptation [7]:

(1) Disuse – the state in which strain is less than that required to maintain healthy bone and thus bone mass and strength are reduced during remodeling

(2) Adaptive state – homeostatic state of bone: bone loss and formation are working at equal rates

(3) Overload – Bone is strained to induce modeling and thus bone mass and strength are increased

(4) Fracture – Strain exceeds its maximum elastic deformation point to induce bone fracture

Table 1 Set point values and corresponding stresses for bone's thresholds for each adaptive state. Adapted from *[8]*

Region of Strain	*Strain Set Point Value*	*Stress*
Disuse	~50-100 με	~1-2 MPa
Adaptive State	~100-1500 με	~20 MPa
Overload	~3,000 με	~60 MPa
Fracture	~25,000 με	~ 120 MPa

MPa = mega Pascal; Ultimate strength of bone is ~25,000 με

Expanding the relationship between strain and bone adaptation, Burr et al. suggest that the magnitude of a bone's adaptive response to loading should be proportional to strain *rate,* rather than strain magnitude, due to the relationship between fluid shear stress on cells and loading rate [5].

The ability of bone to sense and respond to mechanical strain is controlled by a regulatory network of cells: osteocytes, osteoblasts and osteoclasts. [3] Throughout life, bone is continually being modeled and remodeled to meet the needs of its environment via bone formation and resorption (breaking down of bone). Modeling is the process in which bone is formed at one site and broken down in a different location to change its shape and position. Remodeling, on the other hand, involves the removal and replacement of bone at the same site. Most of the adult skeleton is replaced about every 10 years as a result of these adaptive processes.

Osteoblasts and osteoclasts play a crucial role in building and reshaping the skeleton and are activated in response to internal and external signals dictating bone formation or bone resorption. Osteocytes act as sensors of strain to generate signals to the bone surface and stimulate osteoblasts. Osteoblasts work to form new bone, producing collagen and strengthening bone; osteoclasts dissolve bone mineral to remove bone [11]. An increase or decrease in mechanical strain signals a predominance of osteoblast or osteoclast activity, respectively. The net result of these activities can indicate bone loss or gain [26].

In order to describe the modes of mitigating a net bone loss, C.H. Turner concluded that there are three fundamental rules for bone adaptation [27]:

(1) bone adaptation occurs in response to dynamic, versus static, loading;
(2) extending the duration of mechanical loading or exercise has a diminishing effect on further bone adaptation;
(3) bone cells are less responsive to routine loading signals.

These three rules can be extrapolated to design an exercise prescription beneficial to bone by including dynamic, high intensity workouts of short duration with periods of rest. As seen, it is important to understand the fundamentals of bone adaptation when considering bone health countermeasures.

2.3 MEASUREMENT OF EXERCISE

2.3.1 *Ground Reaction Force*

In biomechanics, a common way to study gait analysis or the mechanical loading associated with physical exercise, is to measure ground reaction forces. The ground reaction force, or GRF, is the force exerted on the ground by the mass in contact with it and provides a measure of applied load. Part of the loading on the hip and lower extremities during locomotion is the GRF, generated by the acceleration of the body during impact. In a study on the adaptive skeletal response to mechanical loading, Hsieh, et al. found that strain magnitudes are linearly proportional to the magnitude of the externally applied load. This makes a strong case for the utilization of GRF data to estimate strain magnitude [12].

Force plates are frequently used to measure GRFs. A force plate normally consists of embedded tri-axial force sensors measuring the force between the foot and ground in three axes: medio-lateral, anteroposterior and vertical. The vertical force is the largest component of the GRF and accounts for the acceleration of the body's center of mass [24]. An example of ground reaction force data recorded by a force plate during running is shown in Figure 3.

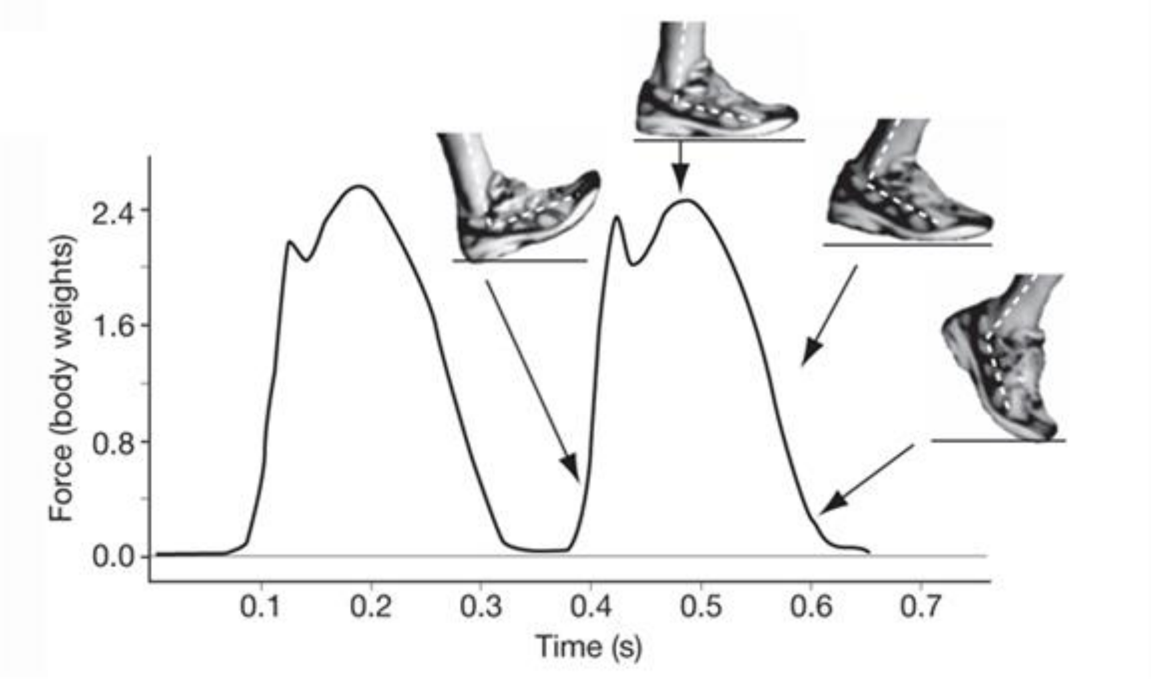


Figure 3 Plot showing typical ground reaction force data (normalized to body weights) recorded on a force plate during running *[16]*

Traditionally, ground reaction forces are the primary means to predict the mechanical stimulus experienced during physical activity. Absent an in-shoe force sensing system, the collection of routine force data for daily activity is impractical, however, due to the need for a force-sensing mechanism such as a force plate. A number of researchers have solved this issue through the utilization of accelerometer-based sensors which are small, unobtrusive and can be worn throughout the day to record activity [6,9,25,28].

2.3.2 *Acceleration Measurements*

Strain magnitudes and strain rates can describe bone's adaptive response to loading. In order to glean information about strain magnitude and rate through the use of accelerometers, the association between strain and acceleration needs to be defined.

The force, *F*, exerted on the ground by a mass in contact with it can be described by Newton's second law ($F = ma$), where a is the acceleration of the effective mass, m. The stress, σ, created by this impact is the force, F, applied to a cross-sectional area, A ($\sigma = F/A$). Strain, ε, the ability of a material to resist deformation, is calculated by Hooke's law ($\varepsilon = \sigma/E$) [11].

The relationship between the strain and acceleration is thus,

$$\epsilon = \frac{m*a}{A*E} \qquad (2.4.1)$$

As mentioned in section 2.2, strain rate (the derivative of equation 2.4.1) is suggested to be strongly related to the osteogenic effect on bone and thus a similar relationship may exist with the acceleration slope (also known as *jerk*, or, the derivative of acceleration). Without a means to measure strain rates experienced in bone, accelerations corresponding to impacts can lend valuable insight into the forces experienced during exercise.

Efforts have been made to determine the relationship between osteogenesis and the accelerations on bone resulting from exercise. Researchers at the University of Oulu in Finland have conducted a series of studies regarding the effect of daily physical activity on bone health in premenopausal women. In each of the studies, daily physical activity was continually recorded with a waist-worn accelerometer. In one study evaluating the contribution of jumping exercise to changes in bone geometry as assessed by quantitative computer tomography (QCT), the researchers found that the subject group performing higher impact exercise showed a high gain in bone circumference at the mid-femur. They concluded that changes in bone geometry are associated with both the number and the intensity (>3.9g) of daily impacts. They also found that certain characteristics of acceleration signals can be a determinant in bone density [1]. One of the characteristics explored was the slope of acceleration, which has already been proposed as a way to obtain information regarding the strain rate above. Additionally, the group looked at the area under the acceleration-time curve to explore whether or not the area and energy of these signals are related to impulse (the area under the force-time curve) and mechanical impact energy, respectively. These signal characteristics were indeed found to have implications for bone health. The signal characteristics and the associated threshold values for positive impact to bone health can be found in Table 2.

Table 2 Minimum acceleration peak signal characteristic values related to changes in bone density according to a study by R. Heikkinen et al.*[11]*

Peak (g)	*Slope* (m/s^3)	*Area* (m/s)	*Signal Energy* (m^2/s^3)
3.9	1000	2	75

2.4 BONE LOSS IN SPACE

Prolonged exposure to reduced gravity environments has been found to have serious detrimental effects on human physiology. In weight-bearing areas such as the hip, crew members have lost up to 1.7% of their bone mass per month as a result of living in microgravity. A compilation of bone loss rates is shown in Figure 4. Bone mineral loss as a result of unloading of the skeleton in microgravity is a significant area of concern due to the increased risk of fracture upon re-exposure to mechanical loading, such as returning to Earth’s gravity field or when exploring other lunar or planetary surfaces. Furthermore, the cumulative deconditioning of bone may put the crew member at an increased risk for developing premature osteoporosis and fractures later in life [21].

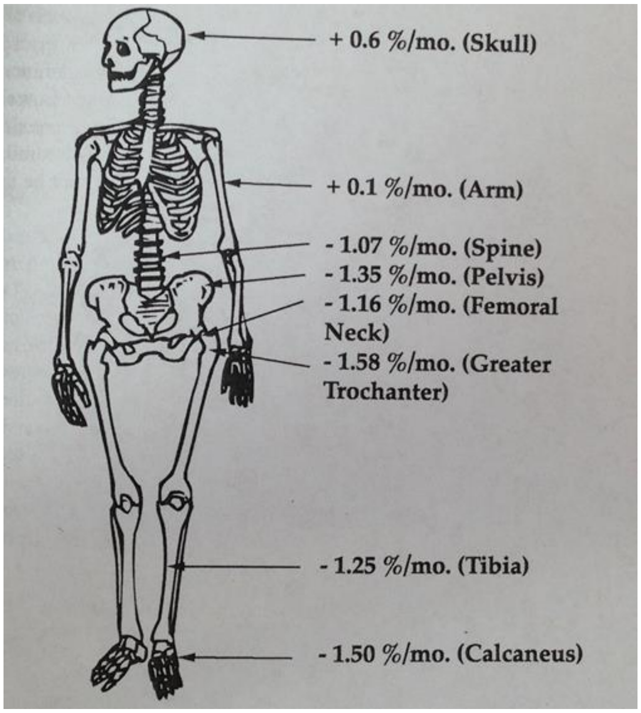


Figure 4 Bone loss rates per month by skeletal region *[21]*

To mitigate bone loss during long-duration space missions, crew members are assigned exercise prescriptions tailored to their training needs. Each of these exercise prescriptions includes aerobic exercise, such as running or cycling, and resistive workout regimes. For resistive exercises, crew members workout on the Advanced Resistive Exercise Device (ARED), shown in Figure 5. The ARED was developed in order to enhance bone and muscle health during long-duration stays on the International Space Station. The ARED is a weight-lifting machine which uses cylinders of air in order to provide resistance up to 600 pound force (lbf), double the load of the previous exercise device, the interim Resistive Exercise Device (iRED). Crew members can perform heel raises using a block, squats, deadlifts, upright row, bicep curls and bench press exercises with the use of this device.

Figure 5 Crew members exercising in microgravity aboard the ISS: running on the T2 treadmill with a subject load device (left) and performing squats on the ARED (right) *[18]*

For aerobic exercise which has benefits for the cardiovascular system, loading of the skeletal system, and maintaining neuromuscular patterns for locomotion, crew members work out on an adapted treadmill. In order to enable locomotion, the crew member is secured to the treadmill via a harness system and subject load device. The treadmill and subject load configuration is shown on the left-hand side of Figure 5. The harness is similar to a commercial backpacking harness where the loads are distributed onto a person’s hips and shoulders. The subject load device applies loads, through the use of bungees, to the crew member similar to those experienced on Earth and the load settings can be changed throughout the mission. It has been suggested that the peak ground reaction force and loading rating achieved during locomotor exercise in microgravity should mimic the same values found on Earth. In order to achieve this and maintain a progressive workout plan, crew members start at approximately 60% of their body weight in the beginning of a mission, working upward to a load of 85-100% of their body weight toward the end.

Crew members are scheduled for two hours of physical activity six days a week, with some of that time including preparation and clean-up. In order to improve the efficacy of exercise countermeasures, the NASA Integrated Resistance and Aerobic Training Study (Sprint) is looking at how to optimize workout regimes utilizing high intensity exercise on both the ARED and treadmill [22], however the ability to regularly and readily monitor the impact on bone health is not available. A means to readily evaluate the mechanical stimulus delivered during new workout regimes would enable researchers with a real-time feedback loop to better understand the loads crew members are experiencing, thus allowing them the opportunity to adapt exercise plans throughout missions.

In addition to the ability to monitor activity in microgravity, more research needs to be done to understand and quantify the effect of impact on bone in order to better inform exercise prescriptions both on Earth and in space related to bone health. Specifically, the number of impacts, the minimum threshold required, and the duration of rest between series of impacts need to be better defined. Once a well-established standard has been developed, flight surgeons and trainers can better define what specific exercises, intensities, and durations of those exercises, are needed in order to protect crew members against bone loss in microgravity.

Chapter 3. OBJECTIVES, AIMS & HYPOTHESES

With the knowledge that peak ground reaction forces, peak loading rates and peak acceleration characteristics are quantifiable ways to measure impacts relevant to bone health, an activity monitoring system has been developed. This system records accelerations corresponding to impacts or loading events during physical activity and is intended for use on the International Space Station or for long-duration space missions to the moon or Mars.

In order to validate the activity monitoring system, a series of experiments were conducted in various 1g and simulated reduced gravity environments over the four-phase NSBRI-funded study "Monitoring Bone Health by Daily Load Stimulus Measurement During Lunar Spaceflights." Throughout the study, operational test experiments, consisting of subjects performing a series of physical locomotor activities, were conducted in three specific gravity environments:

(1) The enhanced Zero-gravity Locomotion Simulator with simulated gravities of lunar (1/6g), Martian (3/8g) and zero gravity;
(2) A parabolic flight allowing for lunar and zero-gravity parabolas;
(3) 1g environment, conducted in a lab setting

This Master's thesis represents phase four of the study. The aims for this phase are as follows:

- Demonstrate the activity monitoring system in an operational, reduced gravity environment, such as a zero-gravity parabolic flight, with associated flight-like hardware in order to progress the system's NASA Technology Readiness Level (TRL) in preparation for flight
- Evaluate and compare force and acceleration results from within and across the various gravity environments to determine the methods of mechanical stimulus prediction in relation to bone health

Additionally, it is hypothesized that:

- There will exist a strong and significant relationship between accelerations recorded at the hip and the peak vertical ground reaction forces recorded during locomotor activities in each gravity condition
- Accelerations recorded at the hip will be comparable across gravity environments for the same activity, allowing the evaluation of osteogenic effects of exercise in reduced gravity when compared to acceleration values observed to benefit bone on Earth

Chapter 4. METHODS

Testing of the activity monitoring system was completed in various gravity conditions, both simulated and real. In each test, subjects were recruited to perform a series of locomotor exercises performed on a treadmill while outfitted with the activity monitoring system to record accelerations associated with their gait. Slow running at 6 mph was the only common activity that was performed in all three gravity environments; slow running (6 mph) and fast running (8 mph) were performed in both the parabolic flight and 1g experiments for comparison.

4.1 EQUIPMENT

4.1.1 *Activity Monitoring System*

The activity monitoring system, manufactured by ZIN Technologies (Cleveland, Ohio), consists of two sensors, each housing a tri-axial accelerometer (+/- 12g), a tri-axial rate gyro (+/- 2000^{o}/sec) and a Bluetooth transmitter. The overall dimensions of each sensor are 40 mm x 22 mm x 12 mm with a packaged mass of 21 grams, including the battery. The sensor shown in Figure 6 is a second-generation device with a sampling frequency of 512 Hz, whereas the first generation sensors had a sampling frequency of 256 Hz. The first generation sensors were used in the eZLS experiment; the second generation sensors were used in the parabolic and 1g experiments.

Figure 6 Activity monitoring sensor

4.1.2 *Force Plate / Data Collection*

In two of the experimental conditions, force data were collected via a force plate (Kistler, Amherst, NY) mounted beneath a treadmill belt. The sampling frequencies for both treadmill force plates were 1000 Hz. It should be noted that when the term “vertical GRF” is used in reduced gravity concepts, the “vertical GRF” is referring to the reference plane normal to the treadmill belt surface and in line with the subject’s coronal plane.

4.1.3 *Compact Subject-Load Device*

The C-SLD is a device designed at the NASA Glenn Research Center in Cleveland, Ohio by ZIN Technologies. The device provides a gravitational replacement load for use on the eZLS treadmill, or future use on a treadmill on the International Space Station. The C-SLD provides load to a subject by placing a small air cylinder in between the attachment points on the subject's harness and the attachment points on the treadmill. The force applied to the subject is varied via a fluid handling system which adjusts the pressure in the cylinders. The air in the cylinders is supplied using a high pressure nitrogen supply bottle which is separate, but connected via a fluid line, from the SLD harness configuration. The load force can be varied from 40 to 225 pounds based upon inputs supplied by a LabVIEW program to obtain the preferred load setting.

4.2 ENHANCED ZERO-GRAVITY LOCOMOTION SIMULATOR

The first of the three gravity environments was conducted in simulated reduced gravity on the enhanced Zero-gravity Locomotion Simulator (eZLS) at the NASA Glenn Research Center in Cleveland, Ohio. The eZLS is a ground-based simulator developed to address physiological effects of microgravity on the musculoskeletal system. The eZLS, which can be seen in Figure 7, consists of a vertically mounted treadmill in which subjects perform activities whilst being suspended horizontally via a harness, subject loading device and series of cables. This simulator mimics the exercise device interfaces found on the International Space Station and enables researchers the ability to study forces which emulate those experienced during exercise aboard the International Space Station.

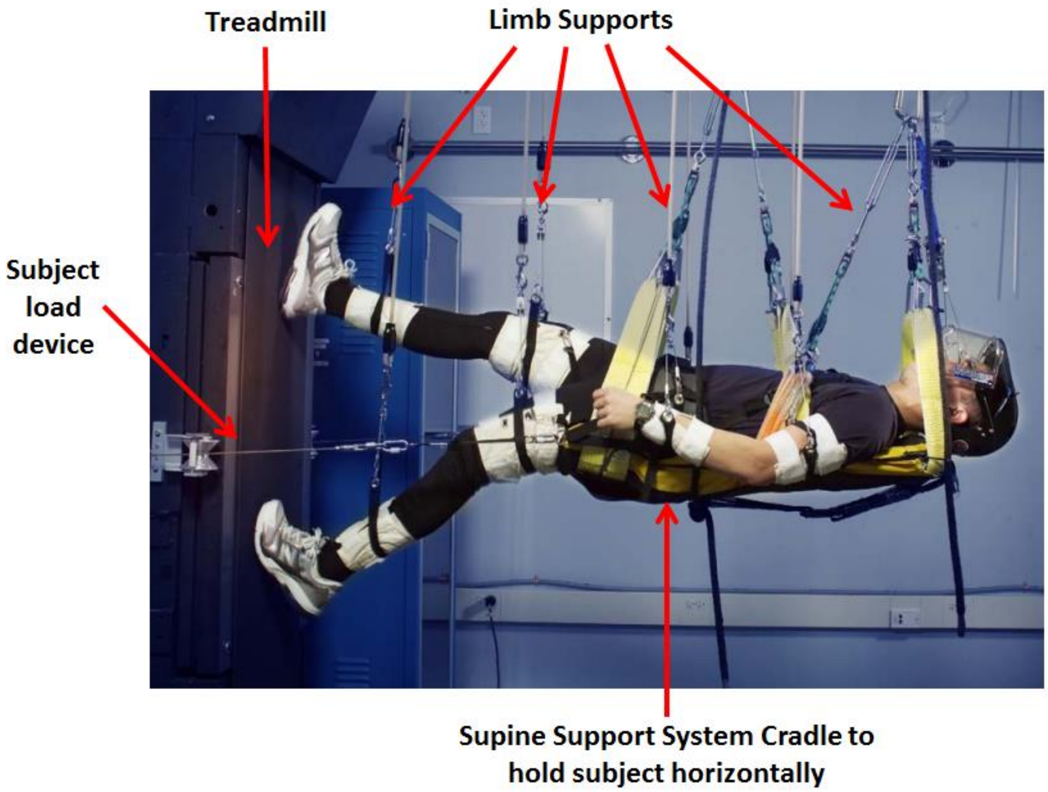


Figure 7 Test subject in the eZLS at the NASA Glenn Research Center

4.2.1 *Test Protocol*

Ten subjects (gender: 6 female/4 male, average age: 34.2, weight: 152 lbs, height: 68 inches) were asked to perform a variety of locomotor exercises while positioned in the eZLS. Subjects performed the following locomotor activities in lunar (1/6g) and Earth (1g) simulated gravities: walking (1MPH), running (6MPH). Ground reaction forces were measured with a force plate (Kistler Corp, Amherst, NY) mounted beneath the treadmill belt at a sampling frequency of 1000 Hz. An activity monitoring sensor was placed in the mid-lower back. Acceleration data were automatically streamed from the activity monitoring system sensors to a computer.

The free body diagram in Figure 8 shows the forces acting on a subject in the eZLS. F_{sss} is the force due to the supine support system cradle suspending the subject in the vertical direction; W is the weight of the subject and associated hardware; $F_{C\text{-}SLD}$ is the force due to the subject load device, C-SLD; F_x is the normal force acting on the subject (in-line with the subject and perpendicular to the treadmill).

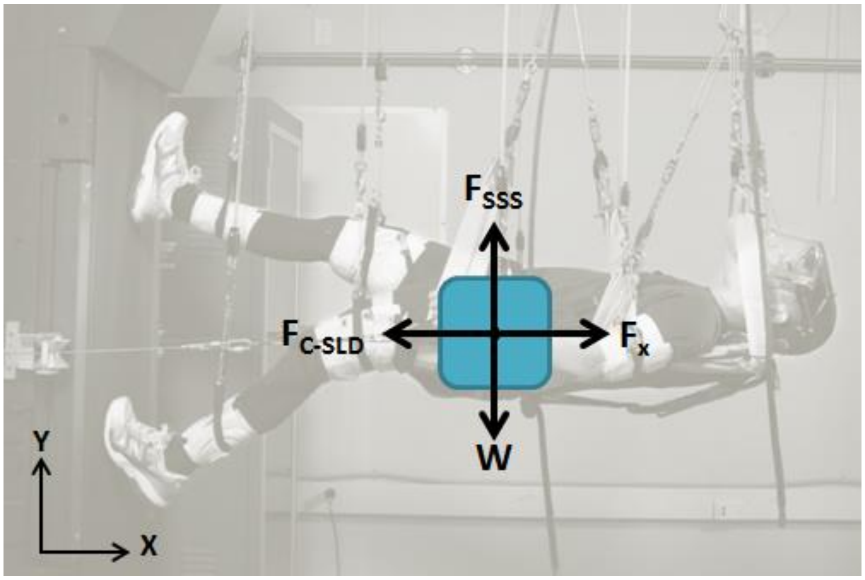


Figure 8 Free body diagram of a subject in the eZLS. Medio-lateral loads are assumed to be zero.

4.3 PARABOLIC FLIGHT

The research team had access to a parabolic flight campaign which demonstrated the activity monitoring system in an operational setting with actual reduced gravity. The reduced gravity experiment was conducted during a four-day parabolic flight campaign in April 2013 at NASA Johnson Space Center's Ellington Field in Houston, Texas. Each flight day consisted of forty parabolas flown over the course of two hours in a modified Boeing 727-200F aircraft. Zero and lunar gravities were experienced. Each parabola consisted of approximately 10-17 seconds of zero-gravity (0.00 g +/- 0.05 g) or 20 seconds of lunar (0.16 g +/- 0.05 g) per parabola.

4.3.1 *Subjects*

Nine subjects (gender: 7 female/2 male, average age: 32.1, weight: 144 lbs, height: 65 inches) were recruited to participate in the experiment. Each subject wore the activity monitoring system while performing a series of locomotor and exercise activities on a treadmill during the flights. Two subjects were tested for two days each, with a primary back-up subject serving as a test operator in the event of motion sickness which can occur on parabolic flights. All subjects were required to pass an Air Force Class III physical exam, meet the subject requirements as determined from a health history questionnaire and sign an informed consent document. The use of human subjects for this experiment was approved by the University of Washington's Institutional Review Board (IRB) and the Johnson Space Center's Committee for the Protection of Human Subjects (CPHS).

4.3.2 *Experimental Setup*

During the parabolic flight campaign, nine test subjects performed a series of locomotor activities with the activity monitoring sensor positioned on the mid-lower back of each subject. The sensor was secured in the pocket of an elastic running belt and positioned in the middle of the back, beneath the iliac crest near the L5 vertebra and can be seen on a subject in Figure 11. The belt was tightened as much as possible, without causing discomfort, to maintain contact with the subject in order to reduce vibration. An instrumented treadmill was mounted to the surface of the aircraft with a frame on the top surface with a cut-out of the ISS treadmill belt dimensions. Subjects wore harnesses similar to those worn by crew members during exercise aboard the ISS and were secured to the surface of the treadmill via the Compact Subject Load Device (C-SLD) to provide loads similar to those experienced on Earth.

Figure 9 Subject running on a treadmill in zero gravity with a 1 body weight (1 BW) load applied via the C-SLD and harness system during a parabolic flight

4.3.3 *Test Protocol*

Baseline data were collected on all subjects in a 1g environment prior to each subject's respective flight. The baseline data included the subject's weight and acceleration data collected during trial runs to help familiarize the subjects with the exercise activities and hardware. Hip accelerations were recorded for slow running (6 mph) and fast running (8 mph).

The free body diagrams shown in Figure 10 show the forces involved in simulated and real gravity condition scenarios during parabolic flight. F_y is the normal force acting on the subject in the vertical direction (in-line with the subject and perpendicular to the treadmill); $F_{C\text{-}SLD}$ is the force due to the subject load device; W_L is the weight of the subject in lunar gravity.

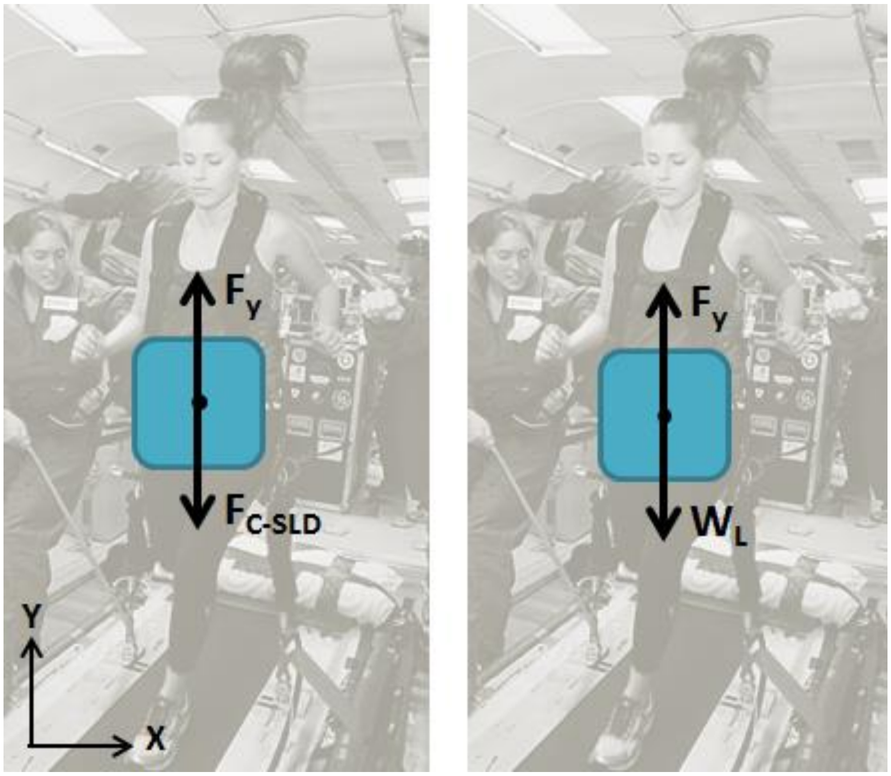


Figure 10 Free body diagram of a subject in parabolic flight. Image on left shows the forces acting on a subject exercising in zero gravity with a subject load device applied with either a 1g or lunar (1/6g) load. The image on the right shows the forces acting on a subject exercising in lunar gravity, with no subject load device applied. Medio-lateral and antero-posterior loads are assumed to be zero.

4.3.4 *Data Collection*

Acceleration data from the activity monitoring system sensor were streamed onto two laptop computers via Bluetooth and recorded through a customized MATLAB code. High-speed video recorded the sagittal plane of the subject while performing activities on the treadmill. Any anomalies with the test trial were also recorded on an Excel spreadsheet.

4.4 1G EXPERIMENT

The last test environment was a 1g lab test experiment conducted at the Computational, Robotics & Biomechanics laboratory in the University of Washington's Department of Orthopaedics in Seattle, Washington.

4.4.1 *Subjects*

A total of nine subjects (average age: 27.2, weight: 135.4 lbs, height: 65 ins) were recruited for this study. All subjects were healthy female distance runners and completed a health history questionnaire that was reviewed with an approved researcher prior to the study to determine eligibility.

4.4.2 *Experimental Setup & Protocol*

All subjects were outfitted with the activity monitoring system sensor positioned on their mid-lower back. The sensor was secured in the pocket of an elastic running belt and positioned in the middle of the back, beneath the iliac crest near the L5 vertebra, shown in Figure 11. The belt was tightened as much as possible to maintain contact with the subject in order to reduce vibration.

After familiarization with equipment and test protocol, subjects performed one-minute trials of slow running (6 mph), and fast running (8 mph) on a treadmill. Three hops were performed prior to each trial in order to synch the force sensor and accelerometer by a single event for post-collection analysis. Each subject's weight was also recorded on the treadmill prior to the exercise trials.

The free body diagram shown in Figure 12 shows the forces involved in simulated and real gravity condition scenarios during parabolic flight. F_y is the normal force acting on the subject in the vertical direction (in-line with the subject and perpendicular to the treadmill); W_L is the weight of the subject.

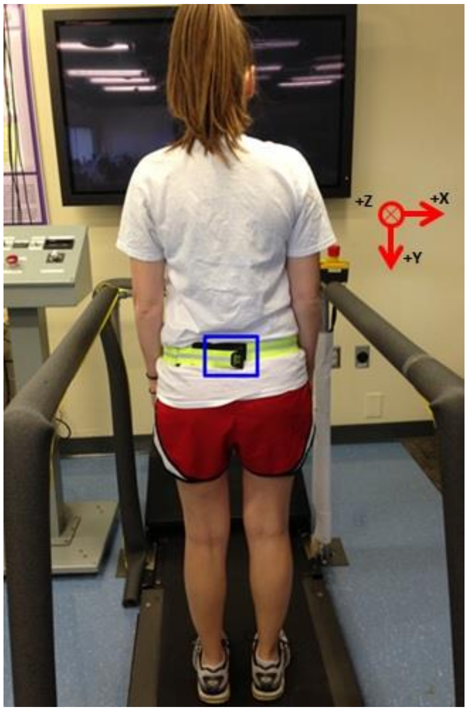


Figure 11 Subject shown on treadmill wearing accelerometer in the mid-lower back; orientation of the sensor axes for both the 1g and parabolic flight are shown to the right of the subject in red

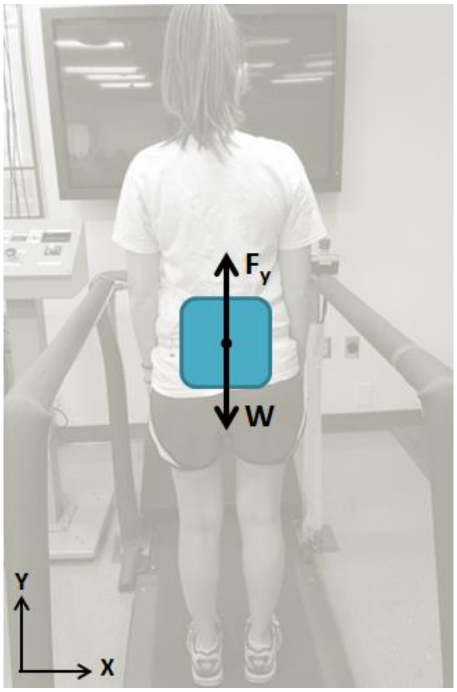


Figure 12 Free body diagram of a subject in the 1G experiment. Medio-lateral and antero-posterior loads are assumed to be zero.

4.4.3 *Data Collection*

Acceleration data from the activity monitoring system sensor was streamed onto a laptop computer via Bluetooth and recorded through customized MATLAB code. Vertical GRF data were also recorded real-time with LabVIEW and saved after each activity trial.

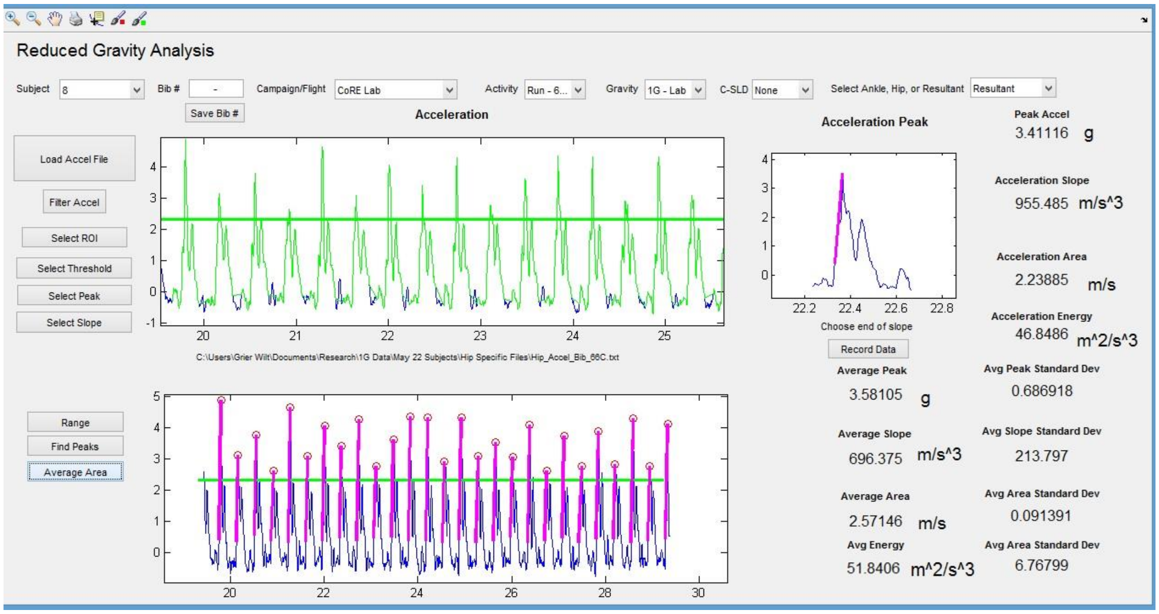
4.5 DATA ANALYSIS

4.5.1 *Reading in the Signals*

A customized MATLAB (version R2012b, Mathworks, Natick, MA) graphical user interface was developed to read in the various force and acceleration signals from all three environmental test experiments. This program was also used to filter and analyze the data. Fourth order zero-phase Butterworth digital filtering was performed on acceleration datasets in the 1g and parabolic flight experiments, with a cutoff frequency of 255 Hz. The sensor used in the eZLS experiment has a sampling frequency of 256 Hz, versus 512 Hz for the sensors used during the parabolic and 1g experiments.

For the acceleration data from the 1g environment experiment, a 1g baseline was subtracted from both the vertical and resultant accelerations, independently.

Figure 13 shows the GUI created to read and process the various experimental signals. Data calculated in the GUI were automatically recorded into a Microsoft Excel spreadsheet for post-processing comparisons. The GUI was designed to automatically detect peaks after a threshold was identified as a result of user input. Using the plot’s x-axis coordinate corresponding to a peak as a reference point, the average distance between peaks, a pre-defined slope threshold value, along with the peak value itself were used to determine the average area, maximum peak value, slope and energy associated with each peak. Standard deviations were also automatically computed. It should be noted that the smaller plot in the upper right-hand corner of the GUI is only for qualitative comparison. To ensure that the average values calculated in the bottom plot made sense and captured representative information, the user has the option to hand-select a representative peak from the desired data set and hand-select the slope start and end points for that single peak. The values for a single peak were recorded in an Excel file, but not used for analysis.


Reduced Gravity Analysis

Subject 8

Bib # -

Campaign/Flight CoRE Lab

Activity Run - 6...

Gravity 1G - Lab

C-SLD None

Select Ankle, Hip, or Resultant Resultant

C:\Users\Grier Wilt\Documents\Research\1G Data\May 22 Subjects\Hip Specific Files\Hip_Accel_Bib_66C.txt

Peak Accel 3.41116 g

Acceleration Slope 955.485 m/s^3

Acceleration Area 2.23885 m/s

Acceleration Energy 46.8486 m^2/s^3

Average Peak 3.58105 g

Avg Peak Standard Dev 0.686918

Average Slope 696.375 m/s^3

Avg Slope Standard Dev 213.797

Average Area 2.57146 m/s

Avg Area Standard Dev 0.091391

Avg Energy 51.8406 m^2/s^3

Avg Area Standard Dev 6.76799

Figure 13 Custom MATLAB GUI used for data analysis showing an acceleration signal and the associated calculations performed on the data set.

4.5.2 *Analyses and Calculations Performed*

Characteristics of acceleration peaks corresponding to impacts, which have been suggested to be osteogenic [13] were calculated for the 1g test data. The characteristics analyzed were: average peak, slope, positive area, and positive energy, and computed as shown in Table 3 and Figure 14. The threshold for acceleration used for calculations was 0.3g as utilized in a prior study analyzing the same acceleration characteristics [11].

Table 3 Acceleration peak characteristics analyzed

Peak Characteristic Analyzed	*Equation*	*Units*
Peak Magnitude	a_{max}	g
Slope	$\frac{da}{dt}=\frac{a_{max}-a_{threshold}}{\Delta t}$	$\frac{m}{s^3}$
Area	$A=\int_{t1}^{t3} a(t)dt$	$\frac{m}{s}$
Energy	$E=\int_{t1}^{t3} \lvert a(t)\rvert^2 dt$	$\frac{m^2}{s^3}$

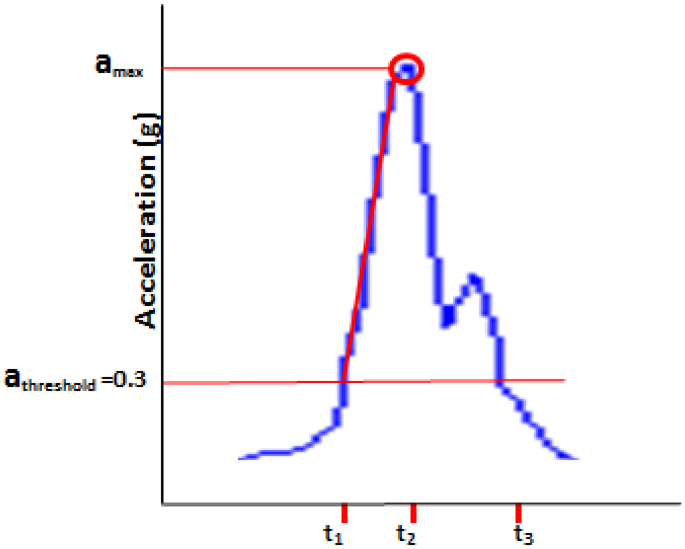


Figure 14 Acceleration peak showing aspects used for calculations; t1 is the time the peak crosses the threshold; t2 the time of maximum acceleration and t3 the time the signal returns below the threshold

When force readings were recorded, average peak and peak loading rates were computed as listed in Table 4. The peak loading rate was taken from a trigger threshold of 25N to the first peak of the GRF corresponding to the initial impact peak; a force peak showing the relevant aspects used for calculations can be found in Figure 15.

Table 4 Force variables analyzed

Force Variables Analyzed	*Equation*	*Units*
Peak Vertical Force	F_{peak}	N
Peak Force Loading Rate	$\frac{df}{dt} = \frac{F_{initial\ impact\ peak} - F_{threshold}}{\Delta t}$	$\frac{N}{s}$

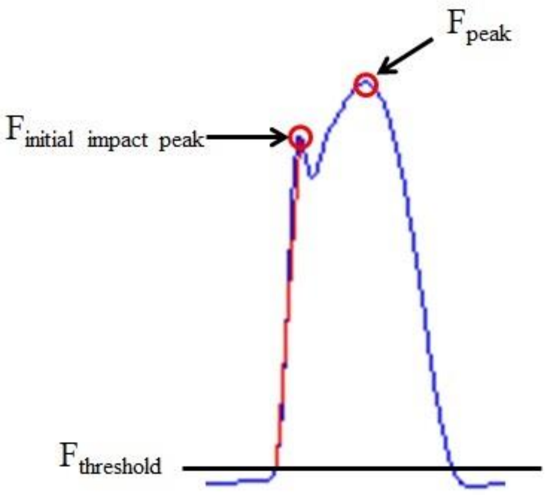
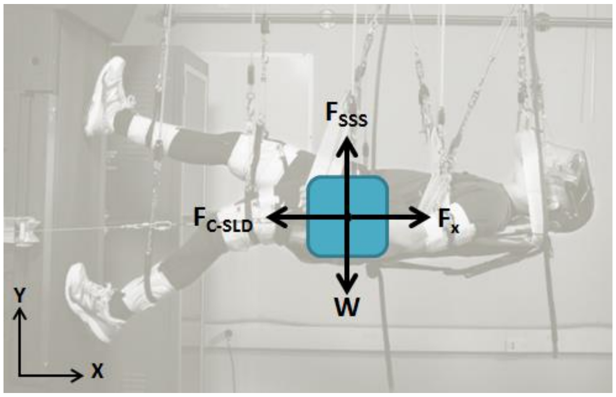


Figure 15 Vertical ground reaction force peak showing aspects used for calculations of the peak vertical GRF and the peak loading rate

4.5.3 *Regression Analysis*

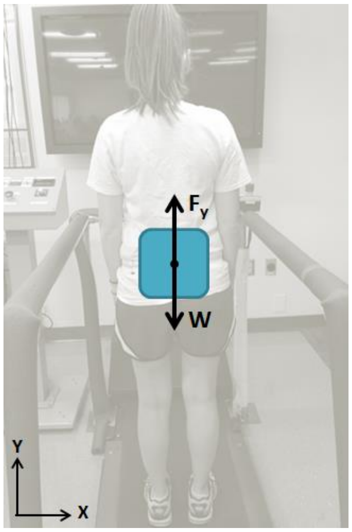
Simple linear regression analysis was completed in Microsoft Excel (2010) on comparable data sets to explore the hypothesis that a positive relationship exists between the peak vertical ground reaction force and acceleration data. Alpha was set at 0.05 for all analyses. A net force ($F_{predicted}$) from the accelerometer measurement was calculated in both the eZLS and 1G environments using the sensor acceleration (in m/s^2) according to the free body diagrams and equations in Figures 16 and 17, respectively. For the eZLS, the total mass includes both the subject's mass and the mass of the eZLS equipment including the harness, helmet, cradle, and cuffs, with a total additional mass of 10.01 kg. For the 1G experiment, gravity is subtracted from the acceleration recorded by the sensor for both the vertical and resultant accelerations (e.g. $a_y = a_{y(measured)} - 1$).



$$F_x - F_{C\text{-}SLD} = m^*a_x$$

$$F_x = (m_{subject}+m_{equipment})^*a_x + F_{C\text{-}SLD}$$

Figure 16 Free body diagram and associated formulas used for the eZLS experiment. F_x is the force predicted from acceleration measurements that can be validated by direct GRF measurements.



$$F_y - m^*g = m^*a_y$$

$$F_y = m_{subject}{}^*a_y + m_{subject}{}^*g$$

Figure 17 Free body diagram and associated formulas used for the 1G experiment. F_y is the force predicted from acceleration measurements that can be validated by direct GRF measurements.

Chapter 5. RESULTS

The activity monitoring system performed well in all three test experiments: accelerations were successfully collected wirelessly in real-time and no data packets were lost during Bluetooth transmission for the duration of the experiments.

5.1 PEAK ACCELERATIONS IN ALL GRAVITY CONDITIONS

Average resultant and vertical peak acceleration data for each test environment and activity are presented in Table 5. All activities compared were performed in a 1g environment or simulated Earth gravity with a 1 body weight (BW) load applied to the subject via the C-SLD. Peak accelerations at the hip varied significantly between the experimental conditions, despite the attempts to apply the same load to the subject. When comparing the same activity, the resultant accelerations were the lowest (0.76 g for slow running) in the eZLS experiment, and highest in the 1g environment (3.8 g for slow running). All peak acceleration values increased with increased locomotion speed. Figure 19 shows the average peak resultant accelerations and respective standard deviations for comparison.

Table 5 Average peak acceleration values for activities performed in simulated or actual 1g environments (vertical acceleration / resultant acceleration, in g's)

Activity	*eZLS (n=10)*	*Parabolic Flight (n=9)*	*1G (n=9)*
Running 6 mph	0.94 / 0.76	1.6 / 3.0	3.5 / 3.8
Running 8 mph	-	1.7 / 3.5	3.8 / 4.2

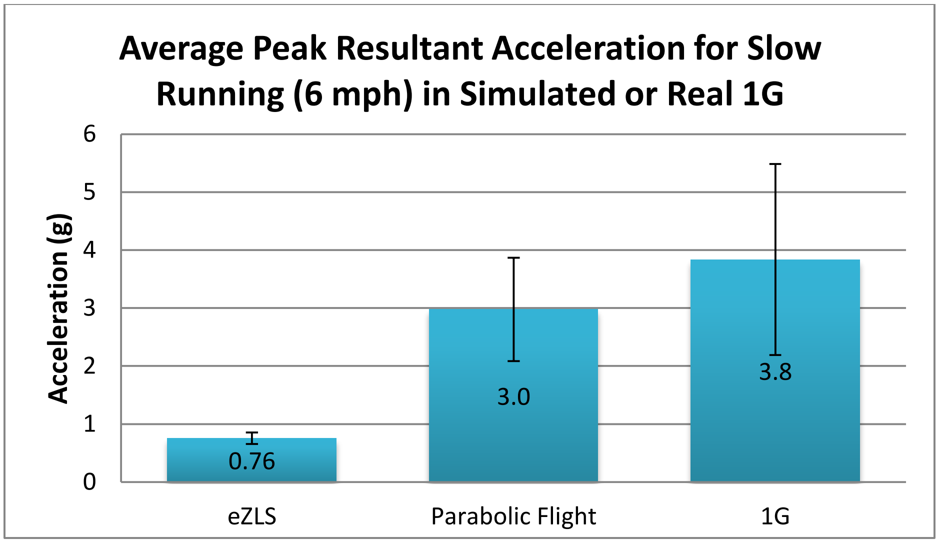


Figure 18 Comparison of average peak resultant accelerations for slow running in a 1g condition (eZLS and the parabolic flight simulated 1g with the aid of the C-SLD)

5.2 PEAK FORCE RESULTS

Average peak force data were collected for each test environment and activity are presented in Table 6. The activities were performed in a 1g environment or simulated Earth gravity with a 1 body weight (BW) load applied to the subject via the C-SLD. Figure 20 shows the average peak vertical GRFs for slow running (6 mph) in the eZLS at a 1g load and in the actual 1g experiment (force displayed is normalized to BW).

Table 6 Average peak vertical GRF values (in body weights) for activities performed in simulated or actual 1g environments

	eZLS	*1G*
Walking (1 mph)	1.3	-
Running (6 mph)	2.1	2.3
Running (8 mph)	-	2.4

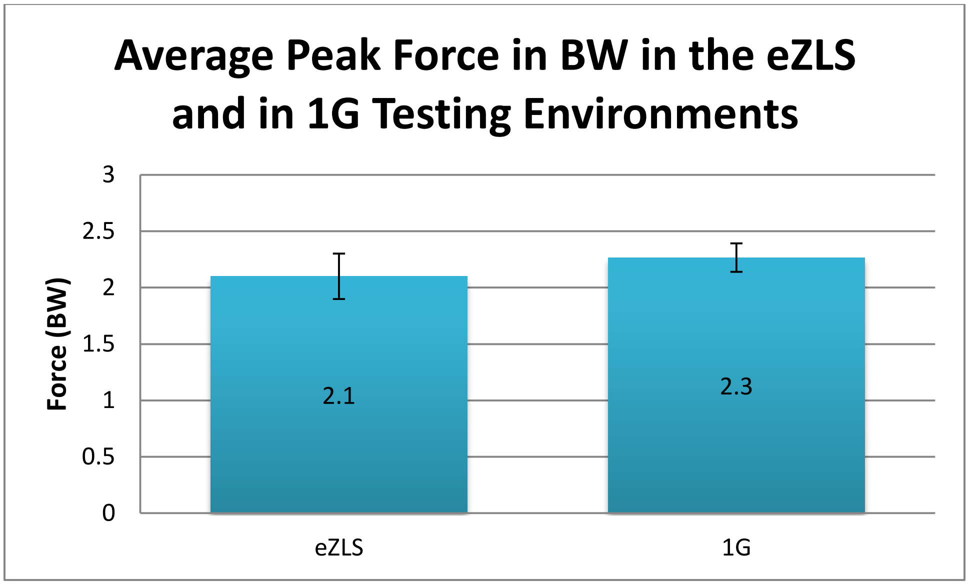


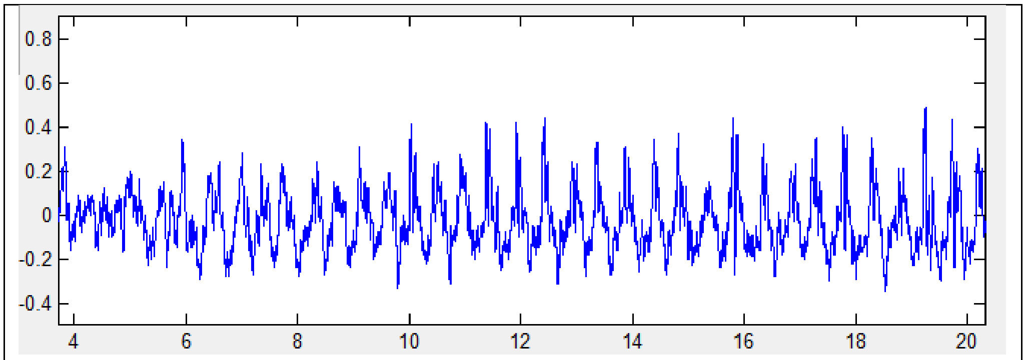
Figure 19 Comparison of measured ground reaction force (in BW) between slow running at 6 mph in simulated 1g in the eZLS and 1g in the lab

5.3 EZLS FORCE VS. ACCELERATION

The average peak resultant acceleration for slow running was 0.76g, significantly less than the values found in the 1g and parabolic experiments (a = 3.8g, a = 3.0g, respectively). The eZLS average peak force reading for slow running (F = 2.1BW), however, was comparable to the GRFs experienced in true 1g (F = 2.3 BW).

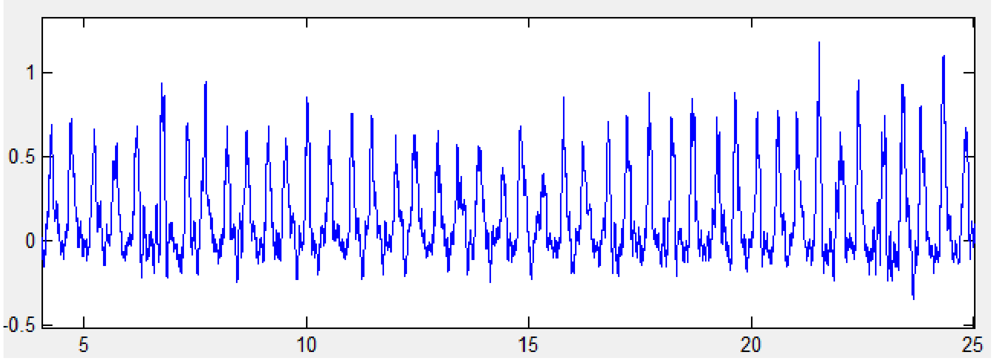
5.4 PARABOLIC FLIGHT ACCELERATIONS

For the parabolic flight, average peak vertical and resultant accelerations were calculated and are listed in Table 5. Additionally, subjects ran (6 mph) in both simulated lunar gravity (a zero gravity condition with a 1/6g load via the C-SLD) and in “true” lunar gravity (1/6g gravity parabola) with no subject load device. The vertical and resultant hip acceleration signals corresponding to these two scenarios for a single subject are shown in Figures 20 and 21, respectively.



Zero Gravity Parabola – 1/6g C-SLD Load

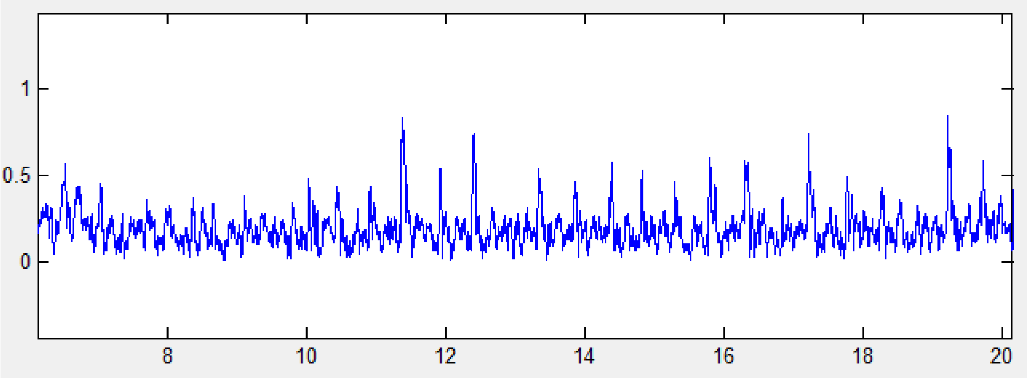
Average peak vertical acceleration = 0.30g



Lunar Gravity Parabola – No C-SLD Load

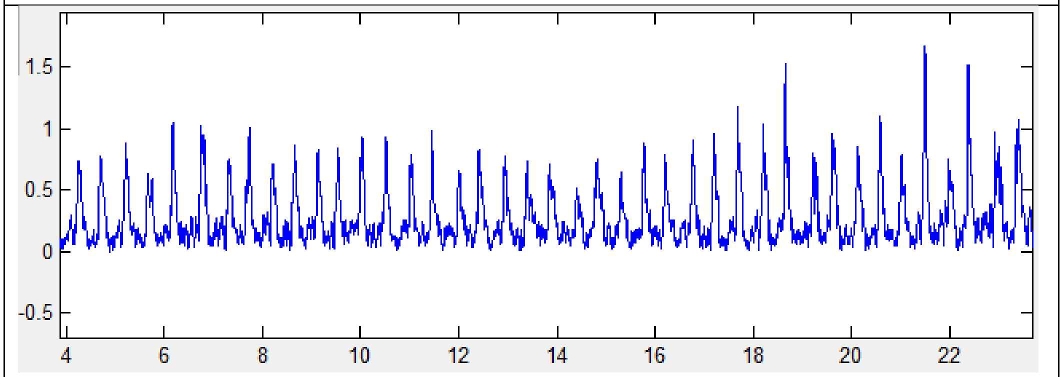
Average peak vertical acceleration = 0.68g

Figure 20 Comparison of slow running for the same subject in a zero gravity condition with a lunar load applied, and a "true lunar" gravity with no subject load applied. Signals shown are vertical accelerations at the hip.



Zero Gravity Parabola – 1/6g C-SLD Load

Average peak resultant acceleration = 0.52g



Lunar Gravity Parabola – No C-SLD Load

Average peak resultant acceleration = 0.90g

Figure 21 Comparison of slow running for the same subject in a zero gravity condition with a lunar load applied, and a "true lunar" gravity with no subject load applied. Signals shown are resultant accelerations at the hip.

5.5 1G ACCELERATION ANALYSIS

Acceleration peak characteristics calculated for the 1g experimental study can be found in Table 6. When comparing the vertical acceleration values to the values of acceleration peak characteristics presented by Heikkinen et al. in Table 1, the only characteristic meeting the determinant threshold for improving BMD was the acceleration slope, with values for slow and fast running greater than 1000 m/s^3.

Table 7 Average acceleration peak characteristic values for activities performed in true 1G environment. The signal characteristic thresholds as identified in [11] are also included for comparison

Activity	*Peak Accel (g)*	*SD*	*Slope (m/s^3)*	*SD*	*Area (m/s)*	*SD*	*Energy (m^2/s^3)*	*SD*
Characteristic Thresholds	>3.9		>1000		>2		>75	
Vertical								
Run (6 mph)	3.51	0.49	1370*	412	1.72	0.093	57.9	7.02
Run (8 mph)	3.80	0.60	1470*	503	1.72	0.099	60.9	8.45
Resultant								
Run (6 mph)	3.84	0.50	715	214	2.33	0.14	53.1	7.00
Run (8 mph)	4.20	0.54	795	280	2.46	0.16	62.0	8.33

*vertical acceleration peak characteristic value above threshold for improving BMD at the hip

5.6 CORRELATIONS

5.6.1 *eZLS Correlations*

Regression analysis was conducted on the eZLS force and acceleration data between peak acceleration and peak vertical ground reaction force ($\alpha = 0.05$). A strong and significant correlation exists between the predicted vertical ground reaction force (as calculated using the vertical acceleration), and the recorded GRF for slow running ($r = 0.87$, $p < 0.001$) and walking ($r = 0.98$, $p < 0.0001$). A strong or significant relationship between the peak vertical acceleration and peak vertical ground reaction force did not exist. Figures 22 and 23 show the relationship between the peak vertical GRF and predicted peak force as calculated from the vertical acceleration, previously explained in section 4.5.3.

Table 8 Relationships between peak vertical ground reaction force and peak vertical acceleration in eZLS for activities performed with a simulated 1g load

Vertical Acceleration	*Walking (1mph)*		*Running (6mph)*	
	R	p-value	R	p-value
Peak Acceleration	0.44	0.21	0.17	0.64
Predicted Force from Acceleration	0.98	<0.0001	0.87	0.001

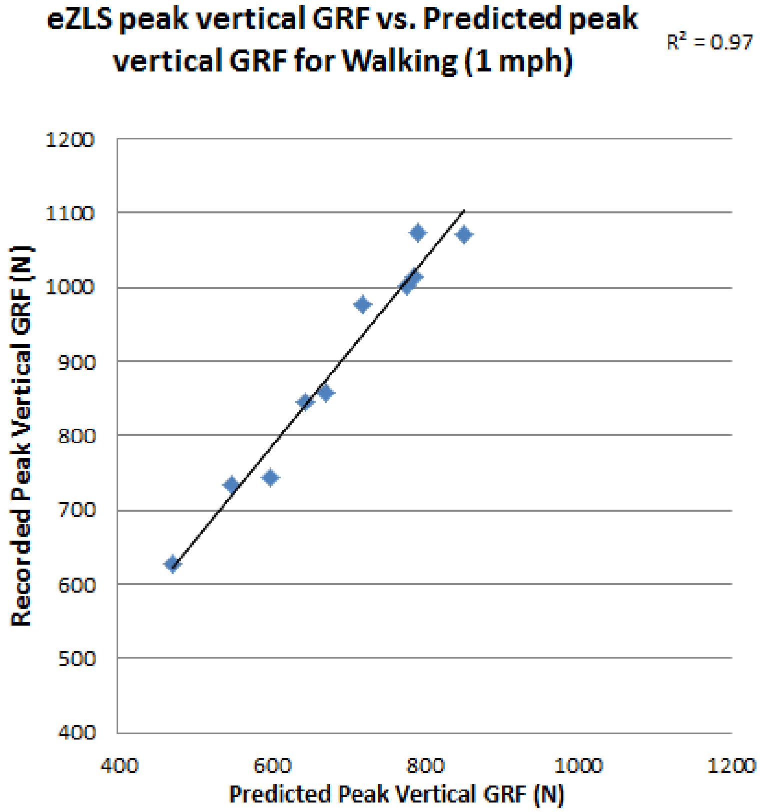


Figure 22 Correlation between recorded vertical GRF force and the predicted vertical GRF using vertical accelerometer data. Data shown are walking (1 mph) in the eZLS

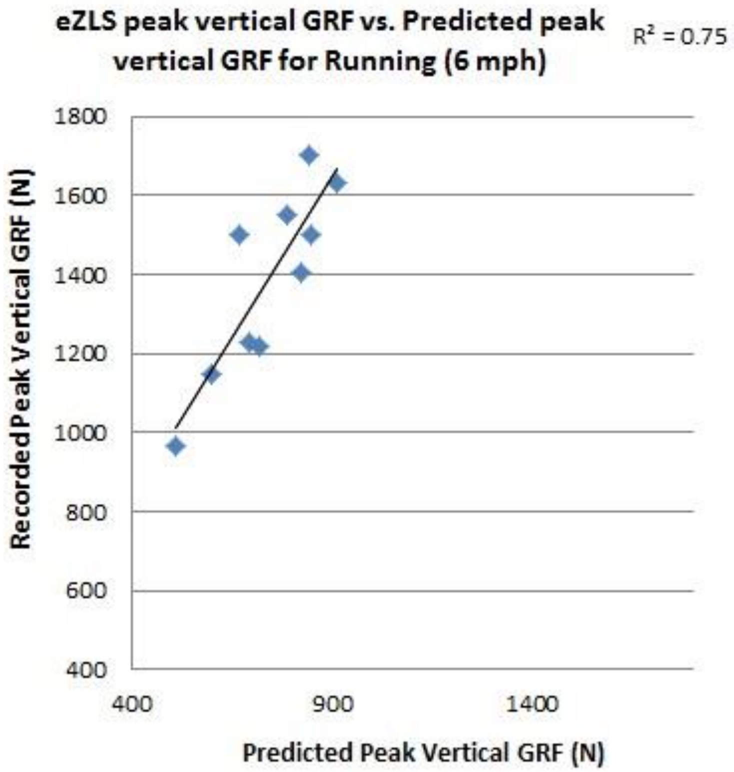


Figure 23 Correlation between recorded vertical GRF force and the predicted vertical GRF using vertical accelerometer data. Data shown are running (6 mph) in the eZLS

5.6.2 *1G Correlations*

Regression analysis (α=0.05) was also conducted on the 1G data sets looking for a correlation between ground reaction force variables: peak vertical GRF and peak loading rate, and acceleration variables: peak acceleration and slope. Correlations between the GRF and acceleration variables are seen in Table 9.

The most significant relationship between acceleration and vertical GRF is when the vertical GRF is predicted using the acceleration of the subject and the force due to gravity (equation 5.4.2). A very strong ($r > 0.79$) and significant ($p < 0.01$-0.05) correlation was found for fast and slow running, using either resultant or vertical accelerations.

Positive relationships were also found to exist between vertical GRF and peak acceleration ($r = 0.66 – 0.73$; p-value < 0.055), as well with peak acceleration slope ($r = 0.61$-0.75) for both slow and fast running.

Using acceleration to predict force loading rate for slow running did not appear to have a significant correlation (p = 0.081 – 0.55); the predictions from acceleration for fast running (r = 0.47 - 0.61) had a more positive correlation, but not significant (p = 0.081 – 0.20).

Table 9 Relationships between peak vertical ground reaction force and force loading rate and accelerations

Acceleration or Predicted Force from Acceleration	*Run (6 mph)*		*Run (8mph)*	
	Vertical Ground Reaction Force Correlations			
	R	p-value	R	p-value
Resultant peak (g)	0.73	0.026	0.67	0.048
Vertical peak (g)	0.73	0.026	0.66	0.055
Resultant slope (m/s^3)	0.75	0.020	0.69	0.038
Vertical slope (m/s^3)	0.71	0.032	0.61	0.079
Resultant predicted force (N)	0.82	0.007	0.80	0.009
Vertical predicted force (N)	0.82	0.007	0.79	0.011
	Peak Force Loading Rate Correlations			
	R	p-value	R	p-value
Resultant peak acceleration (g)	0.23	0.55	0.55	0.12
Vertical peak acceleration (g)	0.27	0.49	0.55	0.13
Resultant slope (m/s^3)	0.34	0.37	0.47	0.20
Vertical slope (m/s^3)	0.26	0.50	0.61	0.081

Chapter 6. CONCLUSIONS & DISCUSSION

6.1 eZLS

As seen in Figure 18 of the Results section, the resultant acceleration recorded for a subject running with a 1g simulated load had a much lower acceleration than a true 1g gravity condition. This could be due to the setup of the simulator. The associated hardware required to emulate a zero gravity environment may negatively influence gait by damping the horizontal excursion of the subject. The sagging and/or tilt of the subject's pelvic region (and therefore the orientation of the sensor) in the eZLS also may be influenced by this hardware. Similar to a mass-spring-damper system, the Supine Support System (SSS) holding the subject horizontal appears to restrain torso motion and may be acting like a pendulum to damp the horizontal excursion, and therefore acceleration recorded on the hip sensor.

This situation is analogous to a stationary leg press where the pelvis, torso and upper extremity are relatively stationary with little to no acceleration at the hip versus free-weight squat exercises where there is vertical excursion and thus acceleration at the hip.

Additionally, it was initially overlooked that the mass of the subject in the eZLS would be significantly different than the subject by his or herself due to the simulator setup. The total mass was then calculated to include the following equipment: cradle, harness, helmet, and cuffs, which have a total mass of 10.01 kg. This amount accounts for an additional 10-20% of the initial mass of the subject and certainly influences acceleration values recorded at the hip, however, it is only a fraction of the difference and does not fully explain the differences.

The hypothesis that there exists a significant relationship between acceleration at the hip and vertical ground reaction forces was found to be true when using the vertical acceleration to predict the ground reaction force in the eZLS. While the acceleration value itself may not have value in reference to GRFs, using it to predict GRF showed strong promise based on correlation values.

6.2 PARABOLIC FLIGHT

The average peak accelerations (both resultant and vertical) were higher for the true lunar gravity than with an applied lunar load. This also suggests that the subject load device is influencing the values recorded at the hip activity monitoring sensor.

The resultant hip accelerations observed during lunar gravities in the parabolic flight experiment (with no subject load device applied to the subject) exhibit the same characteristics as those observed in 1g activities. There was a significant difference between the vertical and resultant accelerations recorded during parabolic flight. The recorded average peak vertical accelerations were approximately half of the average peak resultant accelerations suggesting that the subject has significant acceleration in other axes in addition to the vertical axis. This could be due to the lack of total body and body segment control during locomotion in reduced gravity and it is therefore recommended that resultant acceleration be used when recording accelerations in reduced gravity environments to best capture motion corresponding to impacts.

While the parabolic flight accelerations were recorded, analyzed, and compared to values associated with activity beneficial to bone, this provides little insight into the verification of these accelerations reflecting targeted GRFs. In order to have more confidence in acceleration values recorded at the hip during exercise in microgravity and their relationship to GRFs, further studies should be conducted involving the use of a force plate in order to confirm a relationship between these accelerations and vertical GRFs.

6.3 1G LAB EXPERIMENT

Referring back to the first hypothesis, the regression analysis revealed that a positive and significant relationship exists between accelerations and vertical GRFs and offers insight into which variable of acceleration one should chose to further develop the relationship to predict GRFs.

For the comparison of peak signal accelerations, it should be noted that the peak acceleration signal characteristics were computed for both resultant and vertical accelerations in 1g for this study, but only the vertical accelerations were able to be compared to previous values determined to be beneficial for bone health at the hip as the values Heikkinen et al. reported only correspond to vertical acceleration peaks [4]. It is unknown whether or not these same values would apply to resultant accelerations and this could be explored further to eliminate uncertainty in sensor orientation during ambulatory movement.

For a given activity and environment, only some of the acceleration peak characteristics had values with osteogenic implications. While some of the characteristics for a particular peak had values above the threshold which results in osteogenic benefits, not all did (e.g. a peak might only have an acceleration slope corresponding to an osteogenic value, whereas its energy calculation was below that of an osteogenic energy value). Whether or not these findings are unique to this study is unknown upon review of the literature.

6.4 ACTIVITY MONITORING SYSTEM

Because accelerations are measured in the local coordinate system of the sensor, this has implications for peak value error in a specific axis as the orientation of the sensor may change with tilting of the pelvis or torso. This is of particular significance for the eZLS and parabolic experimental trials as movement during locomotion was observed in all three axes. Sagging and varying pitch of the low-back and pelvic region occur in the eZLS, which would affect the sensor orientation. To eliminate the need to calculate error in rotation of the sensor during locomotion, both vertical (horizontal, corresponding to the vertical acceleration of the subject, in the eZLS) and resultant accelerations were recorded and analyzed in order to eliminate the need to correct for any sensor orientation changes during gait.

Additionally, fixation of the sensor was shown to affect the output acceleration signal; the clarity of the acceleration signal was significantly increased when the sensor was more securely fixed to the subject. The tight fixation of the sensor to the subject helps minimize the visco-elastic effect of tissue between the sensor and bone. When using an externally mounted sensor, the signal can never be truly representative of the acceleration (unless it were directly mounted to the bone of interest), and thus it is essential to ensure the sensor is as tight as possible without causing discomfort.

6.5 SUMMARY

The activity monitoring system has been demonstrated in an operational and flight-like setting to successfully record accelerations during exercise in microgravity. The data presented in this thesis are promising: aside from having the ability to compare acceleration levels to published standards with implications for bone health, the activity monitoring system has also demonstrated that accelerations recorded at the hip have a strong relationship with vertical ground reaction forces, providing additional factors of evaluation for the development of more robust algorithms. The small package size, wireless Bluetooth capability and ability to be unobtrusively worn during exercise or activities of daily living make the activity monitoring system appealing not only for use in space exploration, but also here on Earth. Athletes, physical therapy rehabilitation patients, and the elderly population at risk for bone-related ailments may benefit from using these accelerometers.

The regression analysis data from the 1g and eZLS experiment confirm the hypothesis that there does indeed exist a significant relationship between acceleration recorded at the hip and peak vertical GRF for running. In regards to the second hypothesis, however, it was observed that the accelerations across all three gravity conditions are not directly comparable, making it difficult to develop osteogenic standards of evaluation when compared to studies performed on Earth.

Looking forward, it is suggested that more locomotor and exercise studies utilizing the activity monitoring system be conducted in order to expand the current knowledge base and data supporting activity beneficial to bone health. Further research studies should be conducted with larger and more diverse subject pools to include the male population, increased age ranges, and subjects with varying levels of physical activity. The activity monitoring system may finally enable the research community to develop standard methods to describe physical activity in relation to bone health as a result of raw acceleration.

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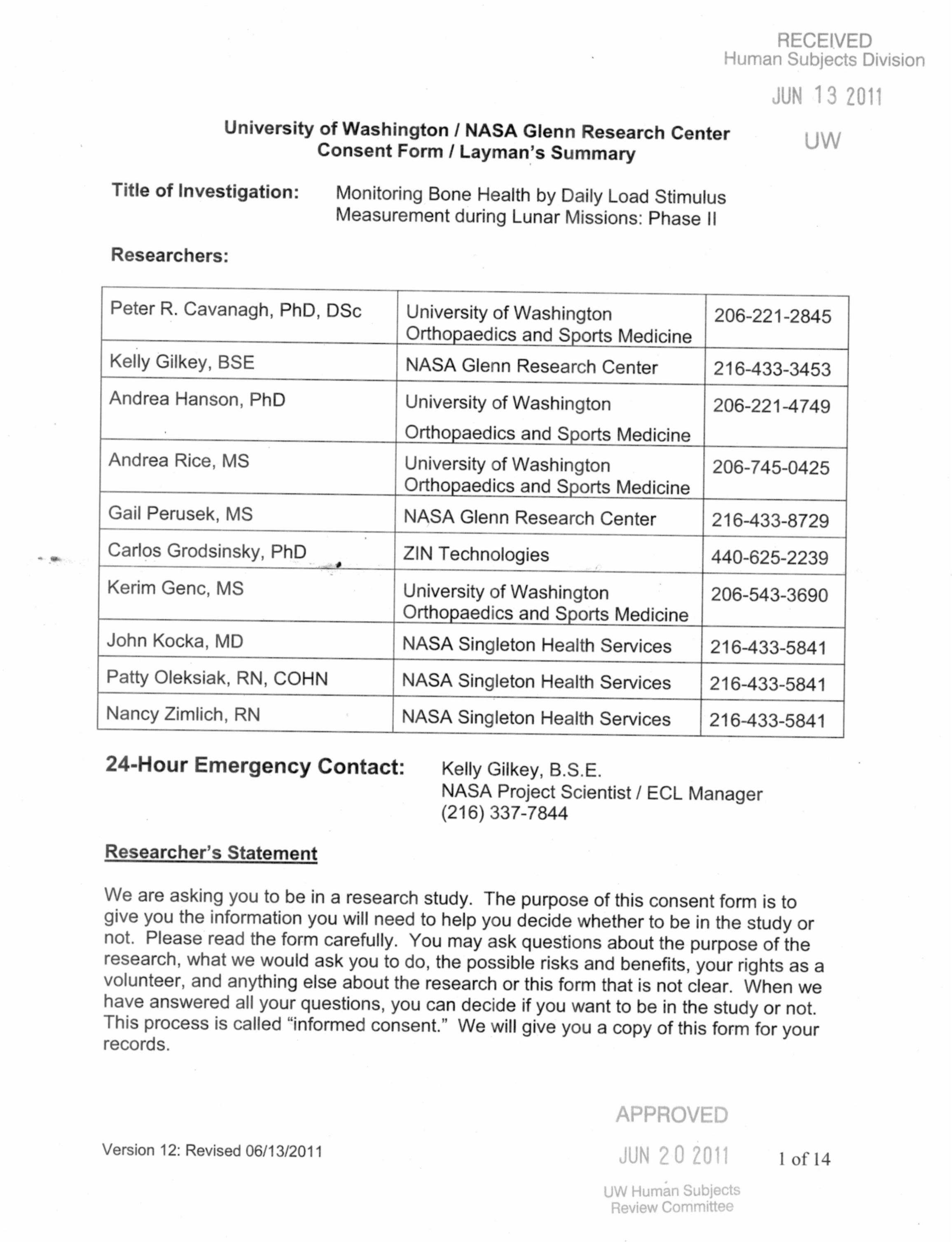
APPENDIX A: EZLS SUBJECT CONSENT FORM



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University of Washington / NASA Glenn Research Center
Consent Form / Layman's Summary

Title of Investigation: Monitoring Bone Health by Daily Load Stimulus Measurement during Lunar Missions: Phase II

Researchers:

Peter R. Cavanagh, PhD, DSc	University of Washington Orthopaedics and Sports Medicine	206-221-2845
Kelly Gilkey, BSE	NASA Glenn Research Center	216-433-3453
Andrea Hanson, PhD	University of Washington Orthopaedics and Sports Medicine	206-221-4749
Andrea Rice, MS	University of Washington Orthopaedics and Sports Medicine	206-745-0425
Gail Perusek, MS	NASA Glenn Research Center	216-433-8729
Carlos Grodsinsky, PhD	ZIN Technologies	440-625-2239
Kerim Genc, MS	University of Washington Orthopaedics and Sports Medicine	206-543-3690
John Kocka, MD	NASA Singleton Health Services	216-433-5841
Patty Oleksiak, RN, COHN	NASA Singleton Health Services	216-433-5841
Nancy Zimlich, RN	NASA Singleton Health Services	216-433-5841

24-Hour Emergency Contact:
Kelly Gilkey, B.S.E.
NASA Project Scientist / ECL Manager
(216) 337-7844

Researcher's Statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

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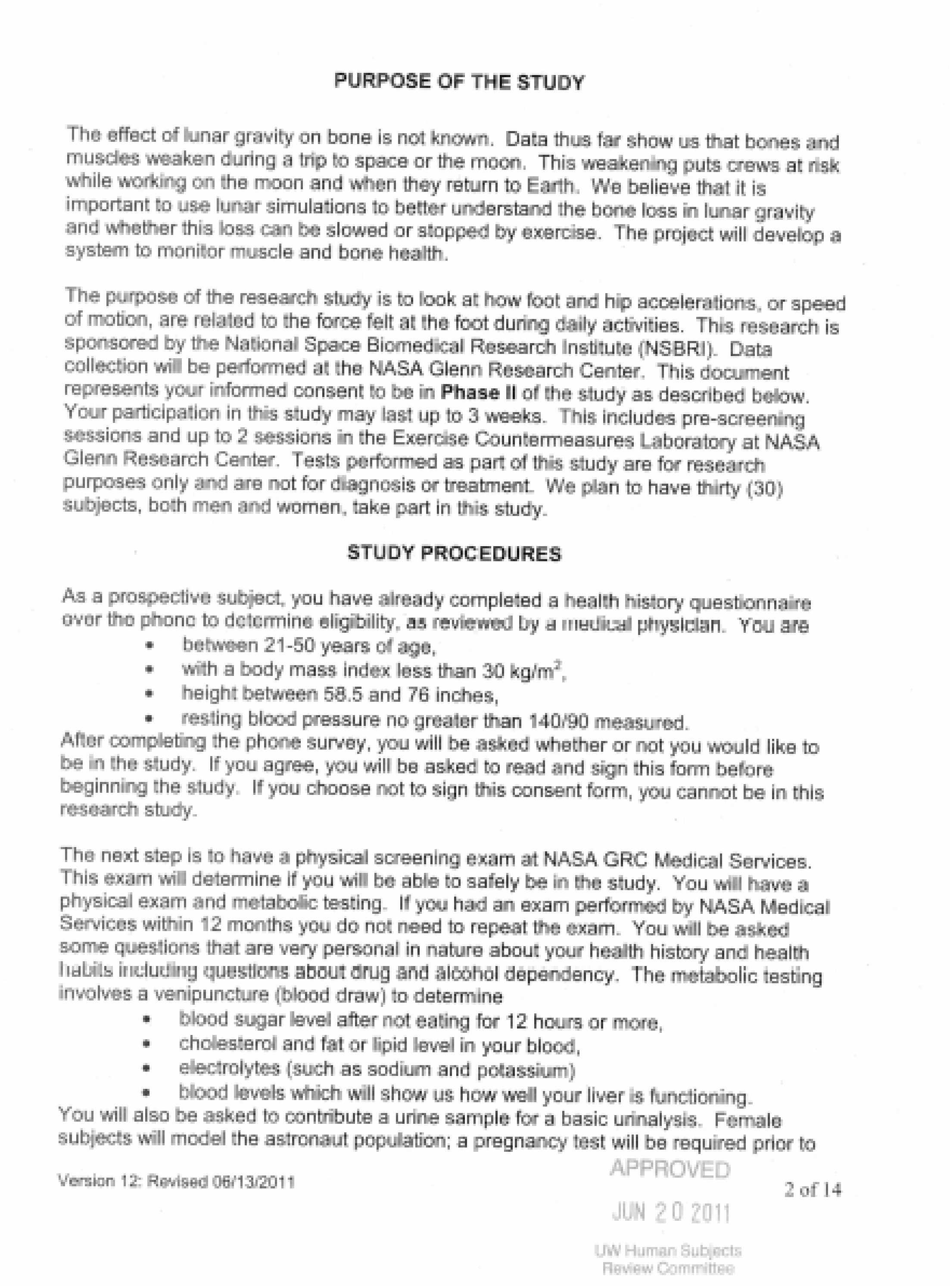
Version 12: Revised 06/13/2011

1 of 14



PURPOSE OF THE STUDY

The effect of lunar gravity on bone is not known. Data thus far show us that bones and muscles weaken during a trip to space or the moon. This weakening puts crews at risk while working on the moon and when they return to Earth. We believe that it is important to use lunar simulations to better understand the bone loss in lunar gravity and whether this loss can be slowed or stopped by exercise. The project will develop a system to monitor muscle and bone health.

The purpose of the research study is to look at how foot and hip accelerations, or speed of motion, are related to the force felt at the foot during daily activities. This research is sponsored by the National Space Biomedical Research Institute (NSBRI). Data collection will be performed at the NASA Glenn Research Center. This document represents your informed consent to be in **Phase II** of the study as described below. Your participation in this study may last up to 3 weeks. This includes pre-screening sessions and up to 2 sessions in the Exercise Countermeasures Laboratory at NASA Glenn Research Center. Tests performed as part of this study are for research purposes only and are not for diagnosis or treatment. We plan to have thirty (30) subjects, both men and women, take part in this study.

STUDY PROCEDURES

As a prospective subject, you have already completed a health history questionnaire over the phone to determine eligibility, as reviewed by a medical physician. You are

- between 21-50 years of age,
- with a body mass index less than 30 kg/m^2,
- height between 58.5 and 76 inches,
- resting blood pressure no greater than 140/90 measured.

After completing the phone survey, you will be asked whether or not you would like to be in the study. If you agree, you will be asked to read and sign this form before beginning the study. If you choose not to sign this consent form, you cannot be in this research study.

The next step is to have a physical screening exam at NASA GRC Medical Services. This exam will determine if you will be able to safely be in the study. You will have a physical exam and metabolic testing. If you had an exam performed by NASA Medical Services within 12 months you do not need to repeat the exam. You will be asked some questions that are very personal in nature about your health history and health habits including questions about drug and alcohol dependency. The metabolic testing involves a venipuncture (blood draw) to determine

- blood sugar level after not eating for 12 hours or more,
- cholesterol and fat or lipid level in your blood,
- electrolytes (such as sodium and potassium)
- blood levels which will show us how well your liver is functioning.

You will also be asked to contribute a urine sample for a basic urinalysis. Female subjects will model the astronaut population; a pregnancy test will be required prior to

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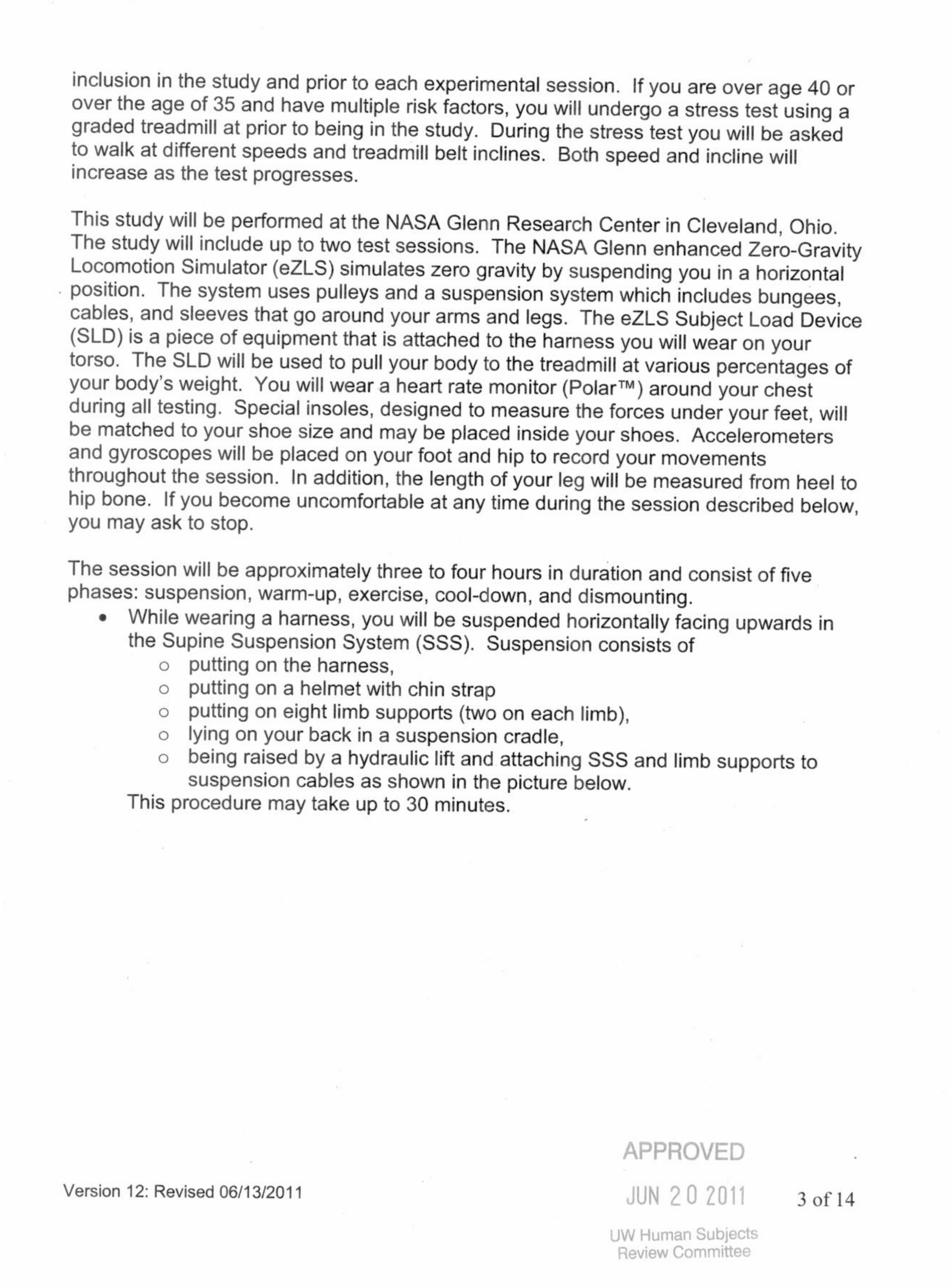


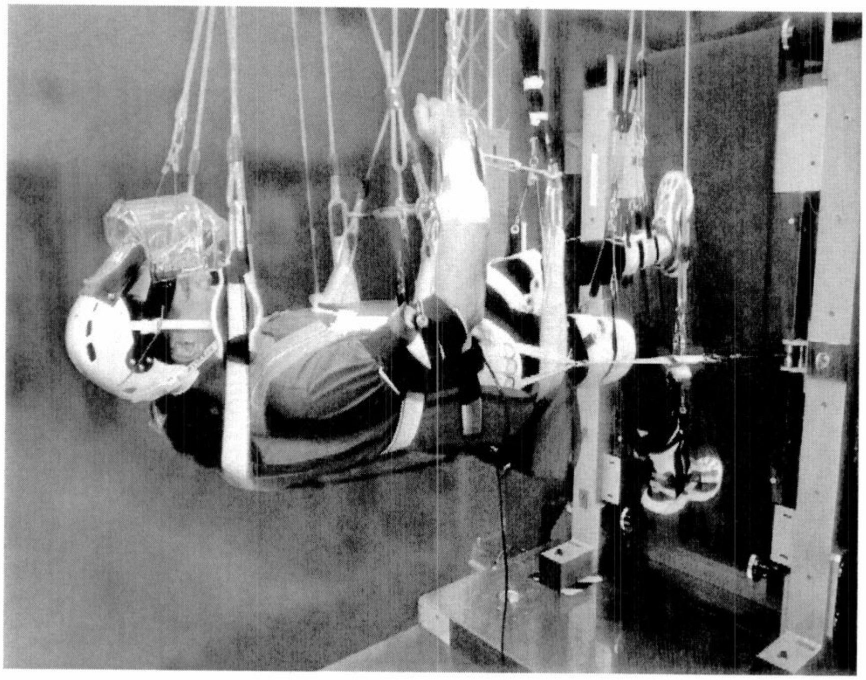
inclusion in the study and prior to each experimental session. If you are over age 40 or over the age of 35 and have multiple risk factors, you will undergo a stress test using a graded treadmill at prior to being in the study. During the stress test you will be asked to walk at different speeds and treadmill belt inclines. Both speed and incline will increase as the test progresses.

This study will be performed at the NASA Glenn Research Center in Cleveland, Ohio. The study will include up to two test sessions. The NASA Glenn enhanced Zero-Gravity Locomotion Simulator (eZLS) simulates zero gravity by suspending you in a horizontal position. The system uses pulleys and a suspension system which includes bungees, cables, and sleeves that go around your arms and legs. The eZLS Subject Load Device (SLD) is a piece of equipment that is attached to the harness you will wear on your torso. The SLD will be used to pull your body to the treadmill at various percentages of your body's weight. You will wear a heart rate monitor (Polar™) around your chest during all testing. Special insoles, designed to measure the forces under your feet, will be matched to your shoe size and may be placed inside your shoes. Accelerometers and gyroscopes will be placed on your foot and hip to record your movements throughout the session. In addition, the length of your leg will be measured from heel to hip bone. If you become uncomfortable at any time during the session described below, you may ask to stop.

The session will be approximately three to four hours in duration and consist of five phases: suspension, warm-up, exercise, cool-down, and dismounting.

- While wearing a harness, you will be suspended horizontally facing upwards in the Supine Suspension System (SSS). Suspension consists of
    - putting on the harness,
    - putting on a helmet with chin strap
    - putting on eight limb supports (two on each limb),
    - lying on your back in a suspension cradle,
    - being raised by a hydraulic lift and attaching SSS and limb supports to suspension cables as shown in the picture below.

  This procedure may take up to 30 minutes.



- If you have not been suspended in the eZLS previously, a brief familiarization session will be held prior to warm-up and data collection. You may spend as much time as needed to become comfortable with locomotion on the eZLS treadmill. Once you have said that you are ready, you will begin a warm-up to get your muscles warmed up.
- Warm-up consists of two minutes of walking (2 mph) followed by three minutes of jogging (5 mph).
- Table 1 outlines a sample test matrix (each session will be randomized).
- The exercise session will consist of a maximum of 18 locomotion trails plus lunar work task trials and squats with the treadmill in a vertical configuration using the SLD. You will perform each exercise for 3 minutes:
    - At 100% of your body weight (BW)
        - walking (2 mph)
        - running (6 mph)
        - squats (8 repetitions)
    - At 1/6th (lunar gravity) and 1/3rd (Martian gravity) of your body weight (BW)
        - walking (2 mph)
        - running (6 mph),
        - loping (2 mph) and
        - hopping (1 mph)

Between trials, you will be allowed to rest or walk at a reduced speed for up to 5 minutes. You may be asked to wear two different pairs of footwear (athletic shoes and analog lunar boots), to examine the effect of sole stiffness on ground reaction force.

You may also be asked to perform lunar work task simulations. These tasks will include:

  - ○ using a modified commercial off-the-shelf stepper to mimic climbing a ladder,
  - ○ jumping down off a surface, no higher than 24 inches, mounted on the treadmill while the treadmill belt is stationary,
  - ○ pulling up on resistive bands attached to the treadmill, to simulate carrying objects,
    - ▪ The loads in the resistive bands will vary between 6 lbs and 20 lbs.
    - ▪ You will be asked to carry this weight the distance of approximately 8 feet.
  - ○ simulating an obstacle path,
    - ▪ Walk at varying speeds from slow to fast walking (approximately 1-3mph) on the eZLS
    - ▪ Follow visual and oral cues to step around and over imaginary objects.
  - ○ performing variable speeds of locomotion with the treadmill.
- Cool-down consists of three minutes of jogging (5 mph) followed by two minutes of walking (2 mph).
- Dismounting consists of lowering and disconnecting you from the subject support system and removing all harness and limb supports. This procedure will take up to 30 minutes.

If all testing conditions cannot be completed in one session, an additional session will be scheduled.

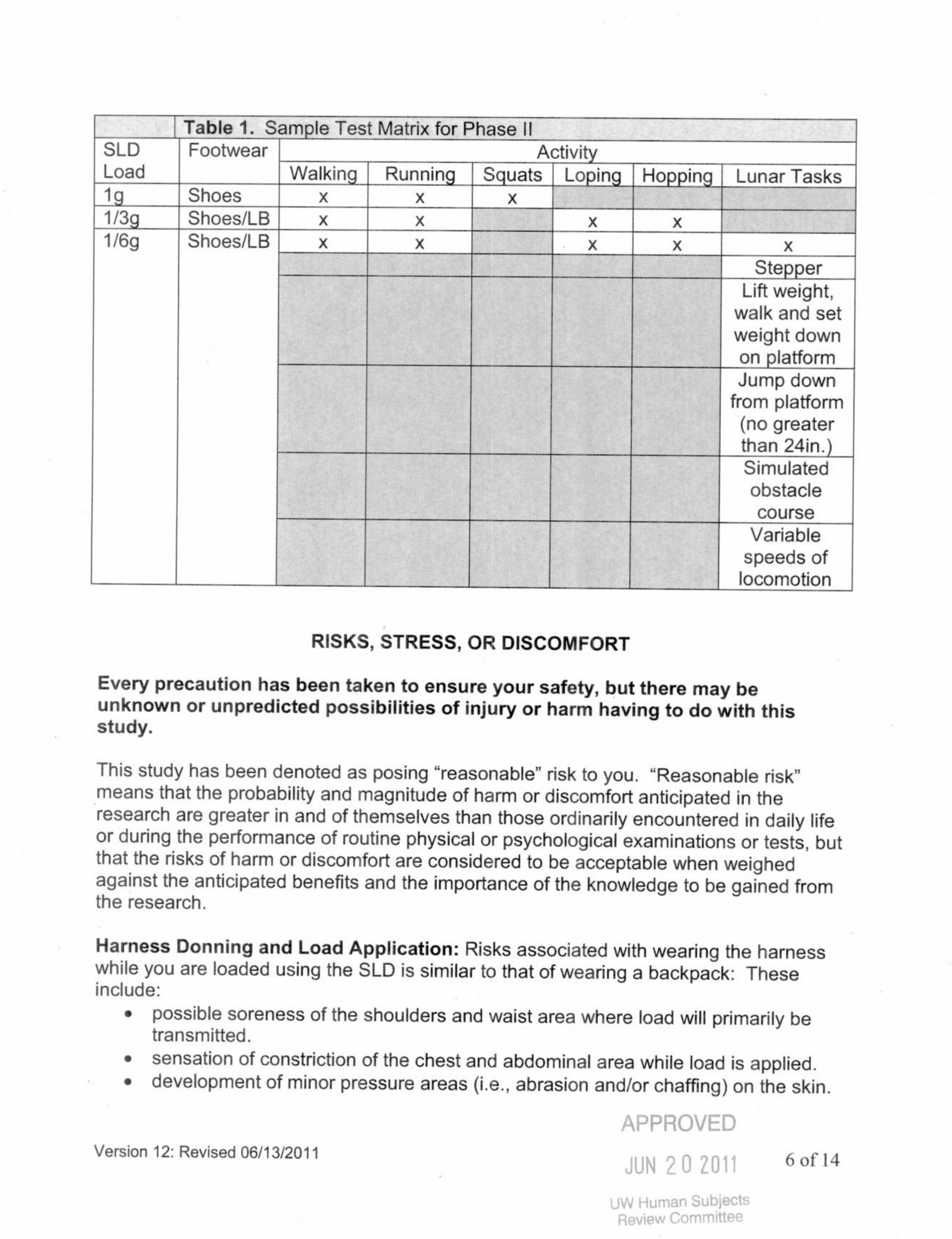


Table 1. Sample Test Matrix for Phase II

SLD Load	Footwear	Activity					
		Walking	Running	Squats	Loping	Hopping	Lunar Tasks
1g	Shoes	x	x	x			
1/3g	Shoes/LB	x	x		x	x	
1/6g	Shoes/LB	x	x		x	x	x
							Stepper
							Lift weight, walk and set weight down on platform
							Jump down from platform (no greater than 24in.)
							Simulated obstacle course
							Variable speeds of locomotion

RISKS, STRESS, OR DISCOMFORT

Every precaution has been taken to ensure your safety, but there may be unknown or unpredicted possibilities of injury or harm having to do with this study.

This study has been denoted as posing “reasonable” risk to you. “Reasonable risk” means that the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

Harness Donning and Load Application: Risks associated with wearing the harness while you are loaded using the SLD is similar to that of wearing a backpack: These include:

- possible soreness of the shoulders and waist area where load will primarily be transmitted.
- sensation of constriction of the chest and abdominal area while load is applied.
- development of minor pressure areas (i.e., abrasion and/or chaffing) on the skin.

- pain due to blood flow constriction from the harness and cuffs. This risk will be reduced by adding padding in the limb cuffs.

You will be able to rest with no force/weight applied from the SLD to your harness if you experience pain. You are encouraged to report any discomfort experienced. Testing may be stopped at any time.

There is a very minimal risk that the subject load device could impart an excessive load on you. This risk has been lessened/minimized by software controls and two emergency stop buttons.

eZLS Suspension/De-suspension: During suspension and the exercise session, there is a slight risk that you could fall from the eZLS suspension device. This is very unlikely since there are redundant supports holding you. There are two supports for the body, two supports for each limb, plus support for your head. All limb and body supports will be attached by a qualified operator to make sure all components are properly worn. For further protection, should you fall an 8-inch mat will be placed directly below you. Such a mat is routinely used for safety in gymnastics. You will also wear a helmet for further protection from falls and from the risk of falling objects. The helmet should be properly attached with a chin strap.

You may experience some discomfort, possibly from abrasion or pinching, while wearing the harness and other supports. Every effort will be made to minimize your discomfort. There is a risk that your clothing could get caught in the treadmill. To reduce this risk, you will wear spandex tights and the motorized drive belt mounted behind the treadmill will be covered with OSHA approved guards. Shoelaces will be tucked inside your shoes. In addition, the hardware is equipped with an emergency stop (E-stop) should any negative event occur.

You will learn hand signals to use during operations. These signals will help you communicate with the research team. This is especially important if the testing makes verbal communication difficult. A “thumbs up” will indicate that you are ready to start or continue. Raising one or both hands will indicate that you need to stop immediately. Procedures are in place should we need to get you out of the eZLS in an emergency. These procedures will be reviewed with you during the familiarization session.

Exercise Sessions: You may experience the usual risks involved with starting an exercise program, these include:

- muscle soreness
- possible muscle cramping,
- soreness and/or joint strain.

The risks associated with the exercise program are likely to be minimal. The load applied will be equal to and less than one body weight. The exercise itself will be no different than jogging and/or running upright on a treadmill. During the object carry simulation, the weight lifted will not exceed 20 lbs. You will be instructed to properly stretch prior to suspension and exercise to prevent possible injury. You will also perform low-load warm-up on the treadmill. Warm-up will insure proper positioning, lessen the possibility of strain, and decrease the degree of muscle soreness. The risk of cramping will be minimized by staying well hydrated. The procedure for requesting and receiving water during exercise will be reviewed with you during the familiarization session. You may stop testing at any time. You should communicate any degree of discomfort to the test operator. The test will be terminated if any of the following occur:

1. You request under any circumstances to stop testing.
2. You report severe pain or injury.
3. You sustain a heart rate above maximum.
4. Equipment malfunction.
5. Unsafe condition perceived by any operator.
6. Subject distress observed by any operator.

There is very minimal risk of occurrence of a cardiac event. Prior cardiovascular disease, smoking, and a recent episode of fatigue or flu-like symptoms are associated with an increased risk of exercise-related acute cardiac events and you should alert the test operator if any of these factors exist. In the event that you experience any chest pain or shortness of breath, exercise will be stopped immediately and 911 will be called. An Advanced Cardiac Life Support (ACLS)-certified physician will be available within 15 minutes of notification via the '911' emergency dispatch system. The risk of a cardiac event will be minimized through the screening procedures and the continuous monitoring of heart rate during exercise. If your heart rate exceeds 85% of your age-predicted maximum the testing will be stopped. You will be allowed to rest prior to restarting any testing. There is an AED (Automatic External Defibrillator) located in the building of the test facility. During all exercise sessions there will be at least 2 Basic Life Support (BLS)-certified and AED-certified team members present.

Equipment: There may be tripping risks associated with the flexible air hoses, electrical power wires and instrumentation cables. This risk is minimized by using guards and cable trays. You will be warned of their location and of the possible hazard. There is a risk of electrical shock from power inputs needed to operate the eZLS. This risk is minimized by following the National Electrical Code (NEC). All facility hardware and safeguards have been approved through the NASA GRC Area 4 Safety Committee, and the Safety Permit shall be active and displayed during these test operations.

Venipuncture (blood draw): The risks of drawing blood from a vein include:

- discomfort at the site of the needle stick,
- possible bruising and swelling around the site of the needle stick,
- rarely an infection, and
- (uncommonly) feeling faint from the procedure.

The total blood loss from the draw will be minimal (approximately 35 milliliters or 2.5 tablespoons) and is not expected to have any negative effects on your body.

Treadmill Stress Testing: The risks associated with the graded treadmill stress testing are minimal. The use of electrodes (wires with sticky patches) for test procedures may cause skin irritation, which is usually minor and resolves quickly. Use of electrodes also

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presents a very small chance of electric shock. All devices will undergo proper safety checks prior to use. During vigorous exercise like that required for the graded treadmill test there is always a remote risk of a heart problem such as an abnormal rate or rhythm or even a heart attack. This is a common procedure used to screen for heart disease, and qualified personnel will be present during this test. The staff and physicians will monitor you closely for any possible side effects caused from exercise. If there is a problem the test will be stopped and you will be evaluated and given treatment if needed.

Confidentiality: There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. More information on confidentiality is provided below in the OTHER INFORMATION section.

ALTERNATIVES TO TAKING PART IN THIS STUDY

The alternative is to not to do this study.

BENEFITS OF THE STUDY

There will be no direct benefits to you but this research will result in the formulation of potential exercise regimens to counter the effects of space flight on bone density and muscle atrophy.

FINANCIAL INTEREST

Peter Cavanagh has an equity interest in ZIN Medical, Inc. which is partly owned by ZIN Technologies, a collaborating institution in this study who is developing the body-worn accelerometer-based sensors used during data collection. This financial interest and the design of the study have been reviewed and approved by the University of Washington. A Management Plan was developed to minimize any possible effect of this financial interest on your safety or welfare. The Plan will also protect the quality and reliability of the research.

OTHER INFORMATION

Privacy and Confidentiality

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. We will label your research data and the information about you with a number, not your name. We will keep your name, address, telephone number, and other information that might identify you separate from your data. The record that links the number with your name will be kept by the NASA Project Scientist. Your physical exam screening data is an exception. Protected health information (PHI) will be recorded as part of your physical exam, including name, date of birth and social security number. This PHI will be kept with your physical exam data. A medical chart will be created for you at NASA Medical Services. Only NASA Medical Services employees will have access to these records. These records will be kept separate from your other study data. People who have access to your medical record may be able to see research test results or procedures that are put in your medical record. In the future, if you give permission to any person or group to look at your medical record (such as an insurance company or employer), they could receive this research information. If you have already given permission to anyone (such as your health insurance company) to look at your medical record, they may receive this research information if they ask for a copy of your medical record.

Your physical exam screening data will be kept for 30 years from the date of collection or for 30 years following the date of retirement if you are a civil servant. This is in accordance with federal record keeping. Physical exam data will be kept for this time even if you do not qualify. The link to your private health information will be destroyed once the full study is completed or by December 31, 2013, whichever occurs first. Your research data (telephone screening and study data) will be kept until these dates even if you do not qualify for participation. The physical exam screening data will not be de-identified.

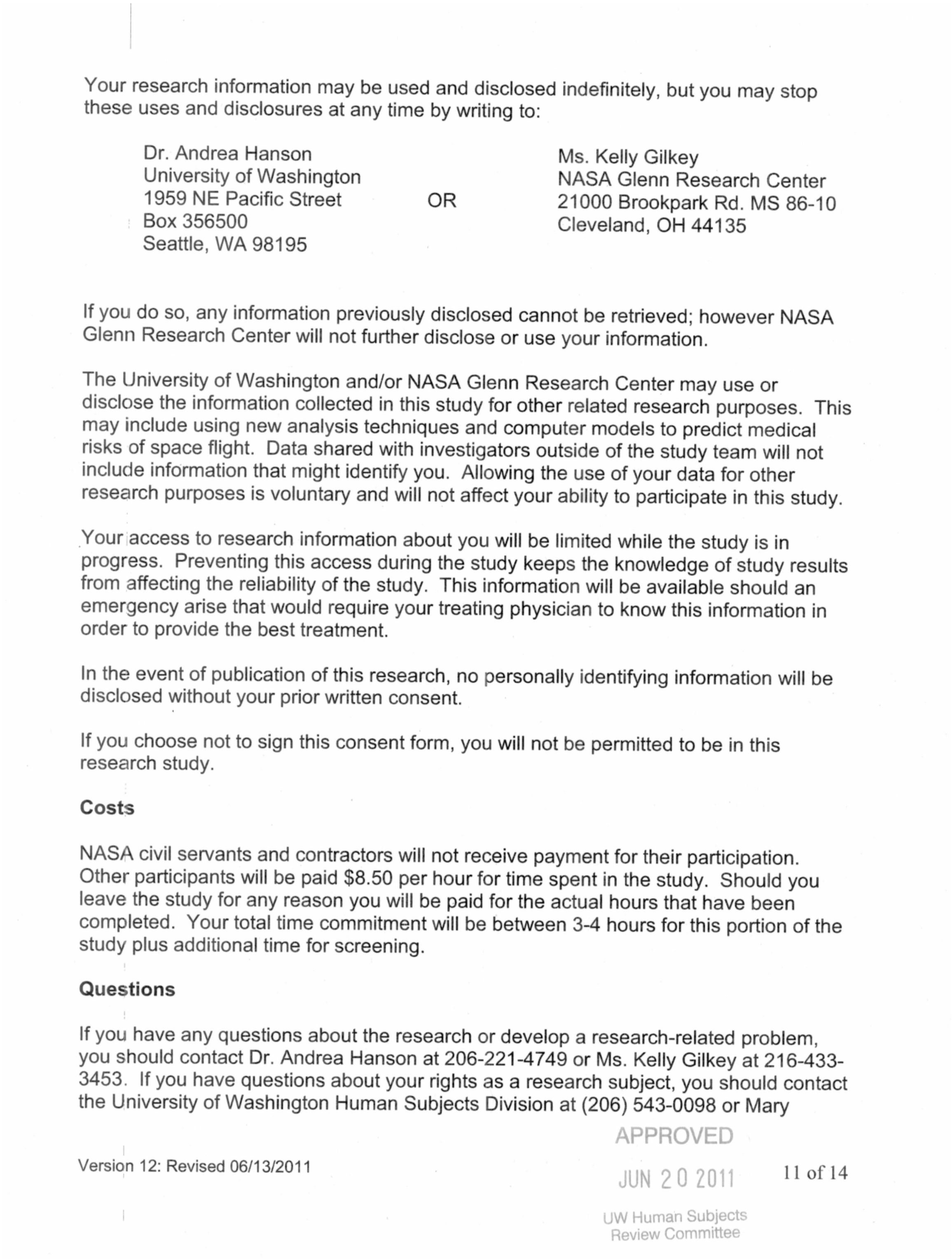
Study records that identify you will be kept confidential as required by law. Federal privacy regulations provided under the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Act of 1974 provide safeguards for privacy, security, and authorized access of your records.

Your research information may be disclosed to:

- the NSBRI, the research study Sponsor and its agents,
- the NASA Glenn Research Center research staff,
- the University of Washington research staff,
- the U.S. Food and Drug Administration,
- and other outside collaborators or laboratories that are participating in this study, if any.

The NASA Glenn Research Center also may use and disclose this information for treatment and payment reasons. The NASA Glenn Research Center must comply with legal requirements that mandate disclosure in certain situations. Otherwise, the information recorded about you as part of this research will be maintained in a confidential manner and will not be disclosed except where required by the Privacy Act of 1974. It is possible that information disclosed about you outside the NASA Glenn Research Center could be re-disclosed and no longer protected by federal privacy laws.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.



Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Dr. Andrea Hanson
University of Washington
1959 NE Pacific Street
Box 356500
Seattle, WA 98195

OR

Ms. Kelly Gilkey
NASA Glenn Research Center
21000 Brookpark Rd. MS 86-10
Cleveland, OH 44135

If you do so, any information previously disclosed cannot be retrieved; however NASA Glenn Research Center will not further disclose or use your information.

The University of Washington and/or NASA Glenn Research Center may use or disclose the information collected in this study for other related research purposes. This may include using new analysis techniques and computer models to predict medical risks of space flight. Data shared with investigators outside of the study team will not include information that might identify you. Allowing the use of your data for other research purposes is voluntary and will not affect your ability to participate in this study.

Your access to research information about you will be limited while the study is in progress. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information in order to provide the best treatment.

In the event of publication of this research, no personally identifying information will be disclosed without your prior written consent.

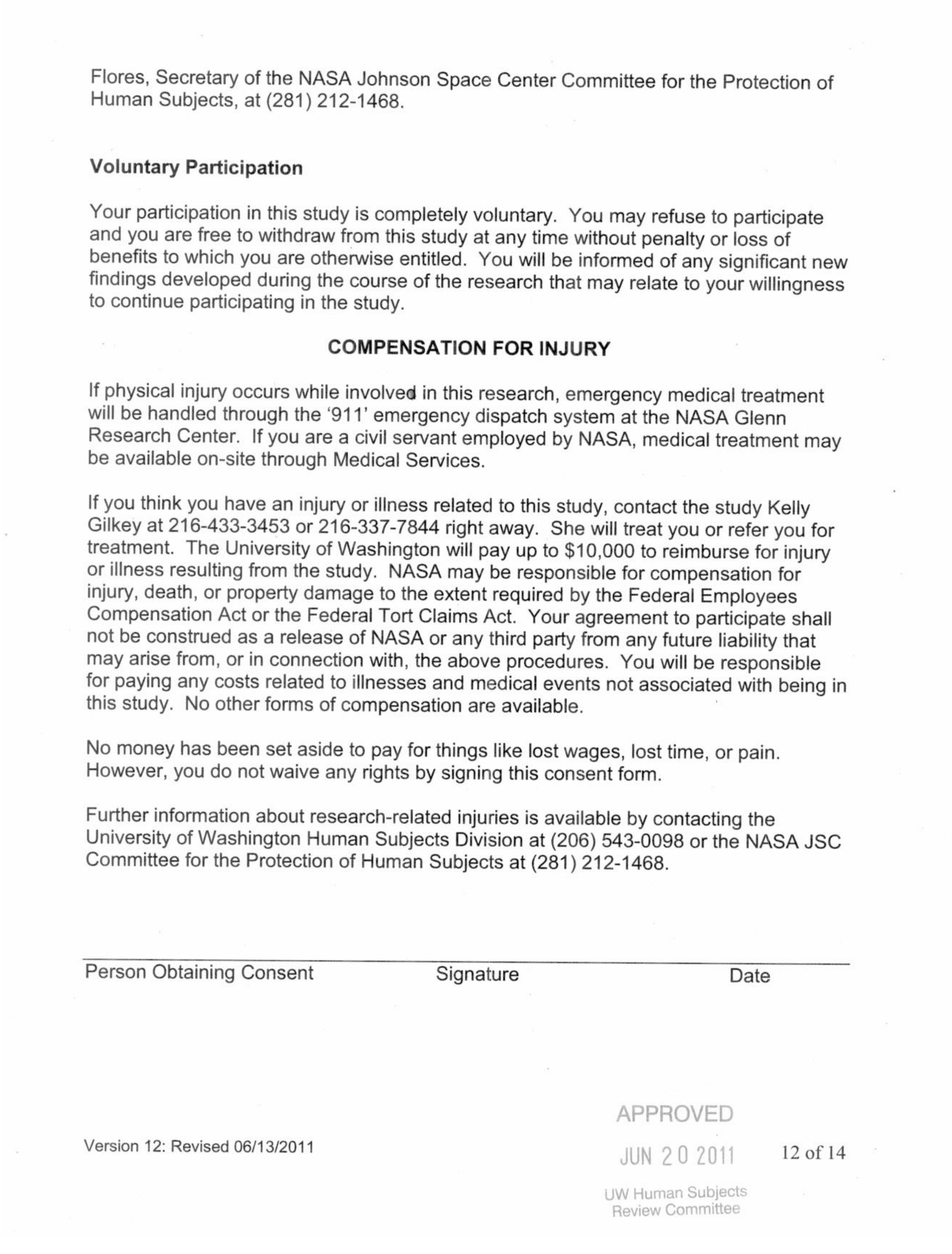
If you choose not to sign this consent form, you will not be permitted to be in this research study.

Costs

NASA civil servants and contractors will not receive payment for their participation. Other participants will be paid $8.50 per hour for time spent in the study. Should you leave the study for any reason you will be paid for the actual hours that have been completed. Your total time commitment will be between 3-4 hours for this portion of the study plus additional time for screening.

Questions

If you have any questions about the research or develop a research-related problem, you should contact Dr. Andrea Hanson at 206-221-4749 or Ms. Kelly Gilkey at 216-433-3453. If you have questions about your rights as a research subject, you should contact the University of Washington Human Subjects Division at (206) 543-0098 or Mary



Flores, Secretary of the NASA Johnson Space Center Committee for the Protection of Human Subjects, at (281) 212-1468.

Voluntary Participation

Your participation in this study is completely voluntary. You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You will be informed of any significant new findings developed during the course of the research that may relate to your willingness to continue participating in the study.

COMPENSATION FOR INJURY

If physical injury occurs while involved in this research, emergency medical treatment will be handled through the '911' emergency dispatch system at the NASA Glenn Research Center. If you are a civil servant employed by NASA, medical treatment may be available on-site through Medical Services.

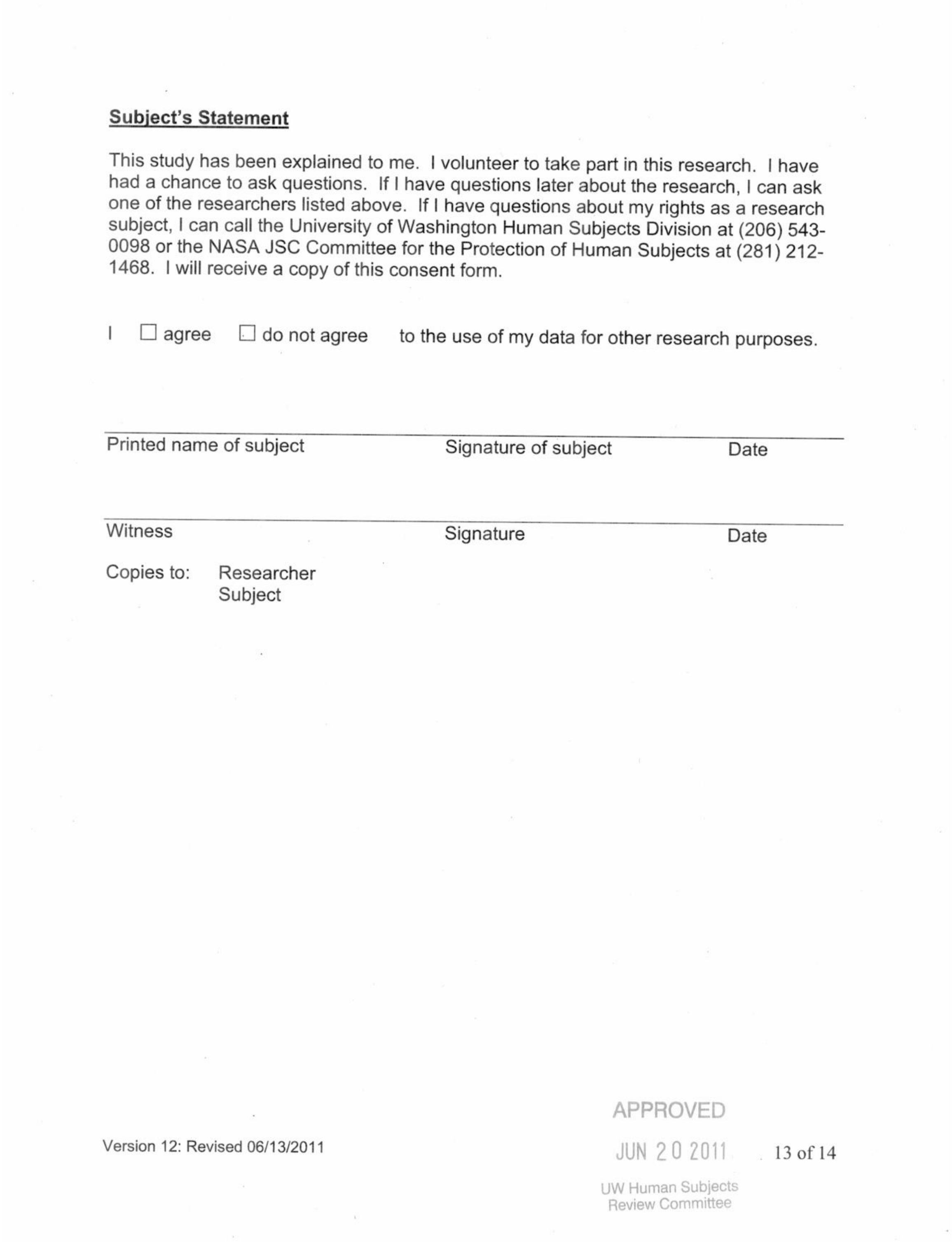
If you think you have an injury or illness related to this study, contact the study Kelly Gilkey at 216-433-3453 or 216-337-7844 right away. She will treat you or refer you for treatment. The University of Washington will pay up to $10,000 to reimburse for injury or illness resulting from the study. NASA may be responsible for compensation for injury, death, or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. Your agreement to participate shall not be construed as a release of NASA or any third party from any future liability that may arise from, or in connection with, the above procedures. You will be responsible for paying any costs related to illnesses and medical events not associated with being in this study. No other forms of compensation are available.

No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form.

Further information about research-related injuries is available by contacting the University of Washington Human Subjects Division at (206) 543-0098 or the NASA JSC Committee for the Protection of Human Subjects at (281) 212-1468.

____

Person Obtaining Consent   Signature   Date



Subject's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the University of Washington Human Subjects Division at (206) 543-0098 or the NASA JSC Committee for the Protection of Human Subjects at (281) 212-1468. I will receive a copy of this consent form.

I ☐ agree ☐ do not agree to the use of my data for other research purposes.

Printed name of subject Signature of subject Date

Witness Signature Date

Copies to: Researcher
Subject

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Videotape/photograph consent

This is to certify that I, ______________________, hereby agree, as a subject in a scientific investigation as an authorized part of the education and research program of the University of Washington under the supervision of Peter Cavanagh, Ph.D., and NASA under the supervision of Kelly Gilkey, M.S., that I may be videotaped or photographed during the course of this experiment.

It is possible that a videotape of my performance or photograph (without name or likeness revealed) may be shown to educational audiences, such as conferences. Videos and photographs will not be used for advertising or media purposes without separate written consent. My consent to be videotaped or photographed is separate from my consent to participate in the investigation.

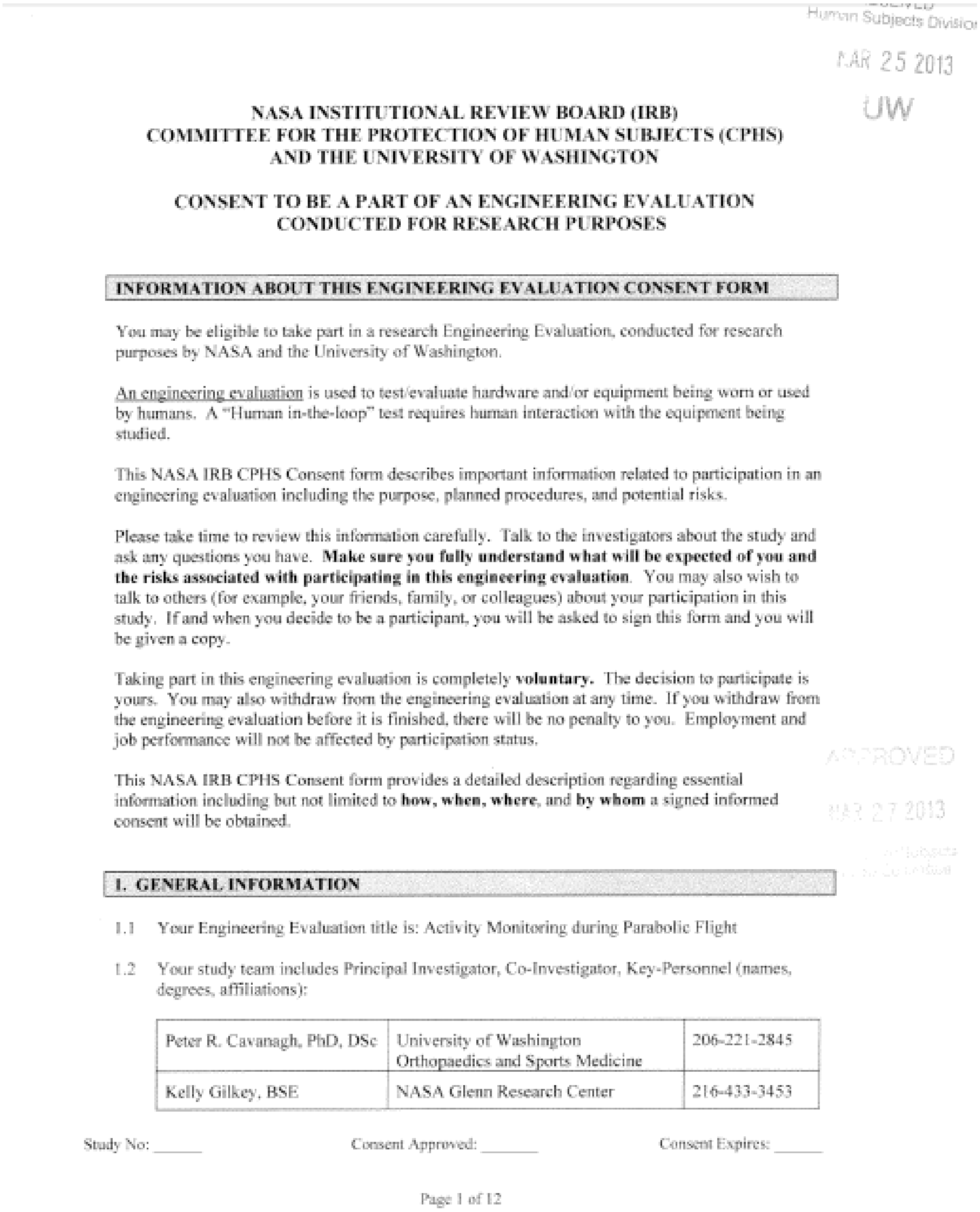
Subject Signature: ____________________________________ Date: ___________

Person Obtaining Consent Signature: ______________________ Date: ___________

Witness: ____ Date: ___________

APPROVED
JUN 20 2011
UW Human Subjects
Review Committee

APPENDIX B: PARABOLIC FLIGHT SUBJECT CONSENT FORM



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MAR 25 2013
UW

NASA INSTITUTIONAL REVIEW BOARD (IRB)
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
AND THE UNIVERSITY OF WASHINGTON

CONSENT TO BE A PART OF AN ENGINEERING EVALUATION
CONDUCTED FOR RESEARCH PURPOSES

INFORMATION ABOUT THIS ENGINEERING EVALUATION CONSENT FORM

You may be eligible to take part in a research Engineering Evaluation, conducted for research purposes by NASA and the University of Washington.

An engineering evaluation is used to test/evaluate hardware and/or equipment being worn or used by humans. A "Human in-the-loop" test requires human interaction with the equipment being studied.

This NASA IRB CPHS Consent form describes important information related to participation in an engineering evaluation including the purpose, planned procedures, and potential risks.

Please take time to review this information carefully. Talk to the investigators about the study and ask any questions you have. **Make sure you fully understand what will be expected of you and the risks associated with participating in this engineering evaluation**. You may also wish to talk to others (for example, your friends, family, or colleagues) about your participation in this study. If and when you decide to be a participant, you will be asked to sign this form and you will be given a copy.

Taking part in this engineering evaluation is completely **voluntary.** The decision to participate is yours. You may also withdraw from the engineering evaluation at any time. If you withdraw from the engineering evaluation before it is finished, there will be no penalty to you. Employment and job performance will not be affected by participation status.

This NASA IRB CPHS Consent form provides a detailed description regarding essential information including but not limited to **how, when, where**, and **by whom** a signed informed consent will be obtained.

APPROVED
MAR 27 2013

I. GENERAL INFORMATION

1.1 Your Engineering Evaluation title is: Activity Monitoring during Parabolic Flight

1.2 Your study team includes Principal Investigator, Co-Investigator, Key-Personnel (names, degrees, affiliations):

Peter R. Cavanagh, PhD, DSc	University of Washington Orthopaedics and Sports Medicine	206-221-2845
Kelly Gilkey, BSE	NASA Glenn Research Center	216-433-3453

Study No: ______ Consent Approved: _______ Consent Expires: ______

Andrea Hanson, PhD	Wyle Laboratories	303-579-4999
Andrea Rice, MS	University of Washington Orthopaedics and Sports Medicine	206-745-0425
Grier Wilt, BS	University of Washington Orthopaedics and Sports Medicine	206-221-3964
Molly Glauberman, MS	University of Washington Orthopaedics and Sports Medicine	206-221-3964
Aaron Weaver, PhD	NASA Glenn Research Center	216-433-3757
Beth Lewandowski, PhD	NASA Glenn Research Center	216-433-8873

1.3 The organization sponsoring or funding the engineering evaluation is: National Space Biomedical Research Institute (NSBRI) and the NASA Flight Opportunities Program.

2. PURPOSE OF THIS ENGINEERING EVALUATION

2.1 You are being asked to join this engineering evaluation because: we have developed a small, wireless activity monitoring system. The purpose of this study is to test the system in a flight analog using parabolic flight. We will test the sensors and characterize the response in this setting.

3. ENGINEERING EVALUATION PARTICIPANTS (SUBJECTS)

3.1 In order to be eligible to participate, you may be asked to undergo the following screening tests or procedures:

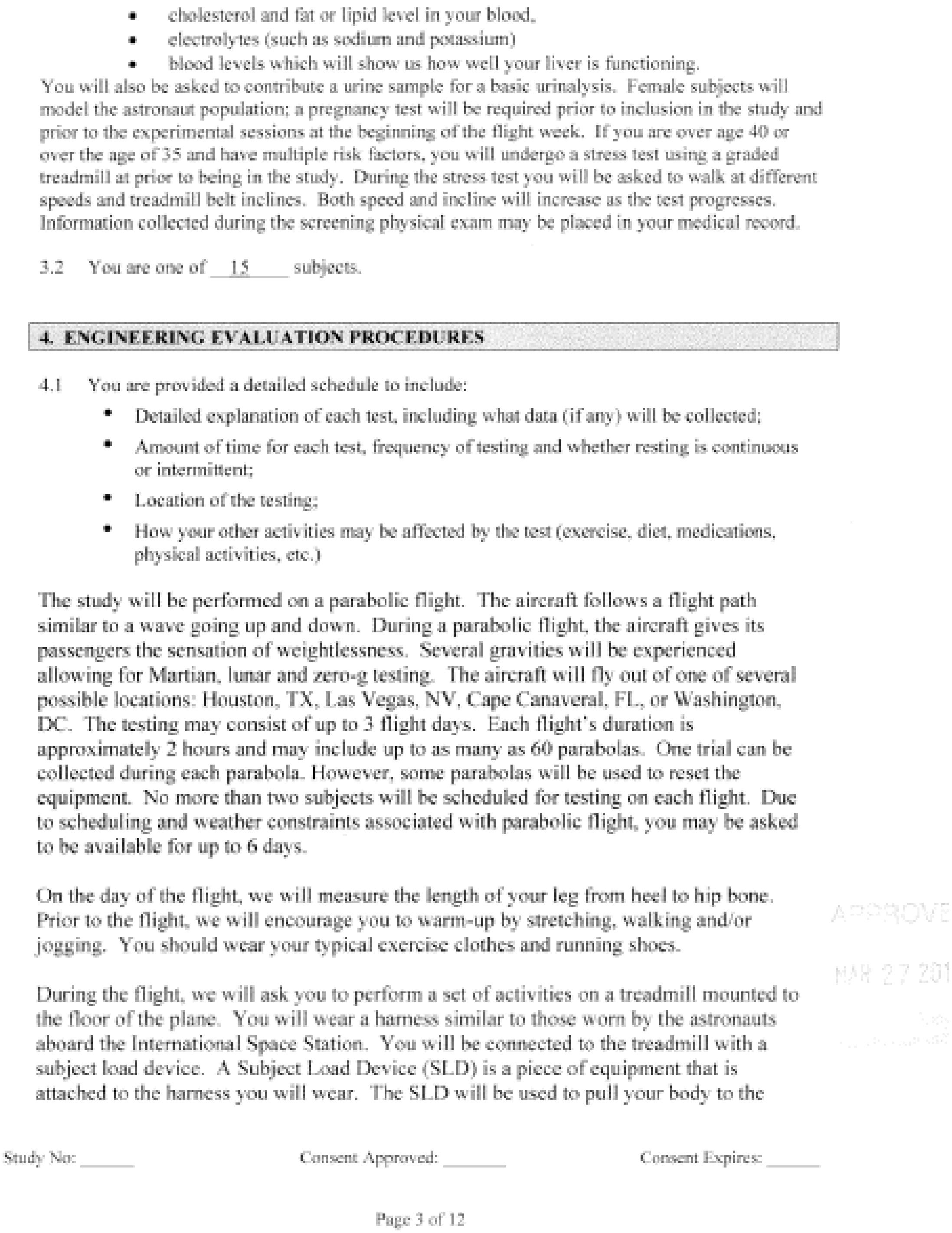
You will complete a health history questionnaire to determine eligibility, as reviewed by a physician. You are

- between 21-50 years of age,
- with a body mass index less than 30 kg/m^2,
- height between 58.5 and 70 inches,
- resting blood pressure no greater than 140/90

After completing the phone survey, we will ask you whether or not you would like to be in the study. If you agree, you will be asked to read and sign this form before beginning the study. If you choose not to sign this consent form, you cannot be in this research study.

The next step is to have a physical screening exam. This exam will determine if you will be able to safely be in the study. You will have a physical exam and metabolic testing. If you had an exam performed by NASA Medical Services within 12 months you do not need to repeat the exam. You will be asked some questions that are very personal in nature about your health history and health habits including questions about drug and alcohol dependency. The metabolic testing involves a venipuncture (blood draw) to determine

- blood sugar level after not eating for 12 hours or more,



- cholesterol and fat or lipid level in your blood,
- electrolytes (such as sodium and potassium)
- blood levels which will show us how well your liver is functioning.

You will also be asked to contribute a urine sample for a basic urinalysis. Female subjects will model the astronaut population; a pregnancy test will be required prior to inclusion in the study and prior to the experimental sessions at the beginning of the flight week. If you are over age 40 or over the age of 35 and have multiple risk factors, you will undergo a stress test using a graded treadmill at prior to being in the study. During the stress test you will be asked to walk at different speeds and treadmill belt inclines. Both speed and incline will increase as the test progresses. Information collected during the screening physical exam may be placed in your medical record.

3.2 You are one of __15___ subjects.

4. ENGINEERING EVALUATION PROCEDURES

4.1 You are provided a detailed schedule to include:

- Detailed explanation of each test, including what data (if any) will be collected;
- Amount of time for each test, frequency of testing and whether resting is continuous or intermittent;
- Location of the testing;
- How your other activities may be affected by the test (exercise, diet, medications, physical activities, etc.)

The study will be performed on a parabolic flight. The aircraft follows a flight path similar to a wave going up and down. During a parabolic flight, the aircraft gives its passengers the sensation of weightlessness. Several gravities will be experienced allowing for Martian, lunar and zero-g testing. The aircraft will fly out of one of several possible locations: Houston, TX, Las Vegas, NV, Cape Canaveral, FL, or Washington, DC. The testing may consist of up to 3 flight days. Each flight's duration is approximately 2 hours and may include up to as many as 60 parabolas. One trial can be collected during each parabola. However, some parabolas will be used to reset the equipment. No more than two subjects will be scheduled for testing on each flight. Due to scheduling and weather constraints associated with parabolic flight, you may be asked to be available for up to 6 days.

On the day of the flight, we will measure the length of your leg from heel to hip bone. Prior to the flight, we will encourage you to warm-up by stretching, walking and/or jogging. You should wear your typical exercise clothes and running shoes.

During the flight, we will ask you to perform a set of activities on a treadmill mounted to the floor of the plane. You will wear a harness similar to those worn by the astronauts aboard the International Space Station. You will be connected to the treadmill with a subject load device. A Subject Load Device (SLD) is a piece of equipment that is attached to the harness you will wear. The SLD will be used to pull your body to the treadmill at various percentages of your body's weight. You will be loaded to various body weights (ranging from 16-100% BW) for testing. We will give you up to 5 parabolas to acclimate to the flight and to familiarize yourself with the activities while on the treadmill.

You will wear a heart rate monitor around your chest during all testing. Special insoles, designed to measure the forces under your feet, will be matched to your shoe size and may be placed inside your shoes. Activity monitoring sensors will be secured to the mid-lower back and around the ankle. If you become uncomfortable at any time during the session described below, you may ask to stop.

We will ask you to perform a variety of activities on a treadmill. These activities may include walking (1-3 MPH), running (5-8 MPH), loping (1-3MPH), hopping (1-3MPH), platform jump down, ladder climb, dead lift, lunge, heel raise, and squat exercises. A cycle may also be mounted to the treadmill for cycling trials conducted at a pace of up to 90 rpm and a load of no more than 125 watts. Between trials, you will be allowed to rest or walk at a reduced speed as needed. The test session will consist of a maximum of 25 trials.

We would like to photograph and video-record the sessions to have an accurate record. When we use the photographs and video recordings outside of the study team, we will digitally edit the images to not identify you. Please indicate below whether or not you give your permission to be photographed and video-recorded. If you do not give permission to have photographs or video footage taken of you, you will not be able to participate in the study.

5. INFORMATION ABOUT RISKS AND HAZARDS

5.1 You are joining an Engineering Evaluation that is:

______"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the tests are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical activities.

__X__"Greater than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the tests are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical activities, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the engineering evaluation.

5.2 You are told that the risks of performing the engineering evaluation and the steps taken to protect against harm include:

Venipuncture (blood draw): The risks of drawing blood from a vein during the screening physical examination include:

- discomfort at the site of the needle stick,
- possible bruising and swelling around the site of the needle stick,
- rarely an infection, and
- (uncommonly) feeling faint from the procedure.

The total blood loss from the draw will be minimal (approximately 35 milliliters or 2.5 tablespoons) and is not expected to have any negative effects on your body.

The risks associated with the graded treadmill stress testing are minimal. The use of electrodes (wires with sticky patches) for test procedures may cause skin irritation, which is usually minor and resolves quickly. Use of electrodes also presents a very small chance of electric shock. All devices will undergo proper safety checks prior to use. During vigorous exercise like that required for the graded treadmill test there is always a remote risk of a heart problem such as an abnormal rate or rhythm or even a heart attack. This is a common procedure used to screen for heart disease, and qualified personnel will be present during this test. The staff and physicians will monitor you closely for any possible side effects caused from exercise. If there is a problem the test will be stopped and you will be evaluated and given treatment if needed.

Since the C-9 or other NASA sponsored aircraft are considered to be a public aircraft within the meaning of the Federal Aviation Act of 1958, as amended, and as such do not hold a current airworthiness certificate issued by the Federal Aviation Administration, any individual manifested to board the C-9 or other NASA sponsored aircraft should determine before boarding whether their personal life or accident insurance provides coverage under such condition.

You may experience motion sickness as a result of the parabolic flight. You may take drugs, such as dramamine, bonine, or antivert, to prevent motion sickness. Mouth/throat dryness may occur as a side effect of these medications. We will encourage you to drink water prior to and following the test to minimize this discomfort.

Risks associated with wearing the harness while you are loaded using the SLD is similar to that of wearing a backpack: These include:

- possible soreness of the shoulders and waist area where load will primarily be transmitted.
- sensation of constriction of the chest and abdominal area while load is applied.
- development of minor pressure areas (i.e., abrasion and/or chaffing) on the skin.
- pain due to blood flow constriction from the harness and cuffs. This risk will be reduced by adding padding in the limb cuffs.

You will be able to rest with no force/weight applied from the SLD to your harness if you experience pain. You are encouraged to report any discomfort experienced. You will wear spandex to create a barrier between the harness and skin in order to reduce friction and the risk of chafing. The harness also features padded regions so as to minimize the risk of bruising. Testing may be stopped at any time.

You may experience the usual risks involved with an exercise program, these include:

- muscle soreness
- possible muscle cramping,
- soreness and/or joint strain.

The risks associated with the exercise program are likely to be minimal. The load applied will be equal to and less than one body weight. The exercise itself will be no different than jogging and/or running upright on a treadmill. You will be instructed to properly stretch prior to testing, during breaks between the sets of parabolas and after the test to prevent possible injury. Warm-up will lessen the possibility of strain, and decrease the degree of muscle soreness. The risk of cramping will be minimized by staying well hydrated. The procedure for requesting and receiving water during exercise will be reviewed with you during the familiarization session. You may stop testing at any time. You should communicate any degree of discomfort to the test operator. The test will be terminated if any of the following occur:

1. You request under any circumstances to stop testing.
2. You report severe pain or injury.
3. You sustain a heart rate above maximum.
4. Equipment malfunction.
5. Unsafe condition perceived by any operator.
6. Subject distress observed by any operator.

There is very minimal risk of occurrence of a cardiac event. Prior cardiovascular disease, smoking, and a recent episode of fatigue or flu-like symptoms are associated with an increased risk of exercise-related acute cardiac events and you should alert the test operator if any of these factors exist. In the event that you experience any chest pain or shortness of breath, exercise will be stopped immediately and the flight surgeon will be notified. The risk of a cardiac event will be minimized through the screening procedures and the continuous monitoring of heart rate during exercise. If your heart rate exceeds 85% of your age-predicted maximum the testing will be stopped. You will be allowed to rest prior to restarting any testing.

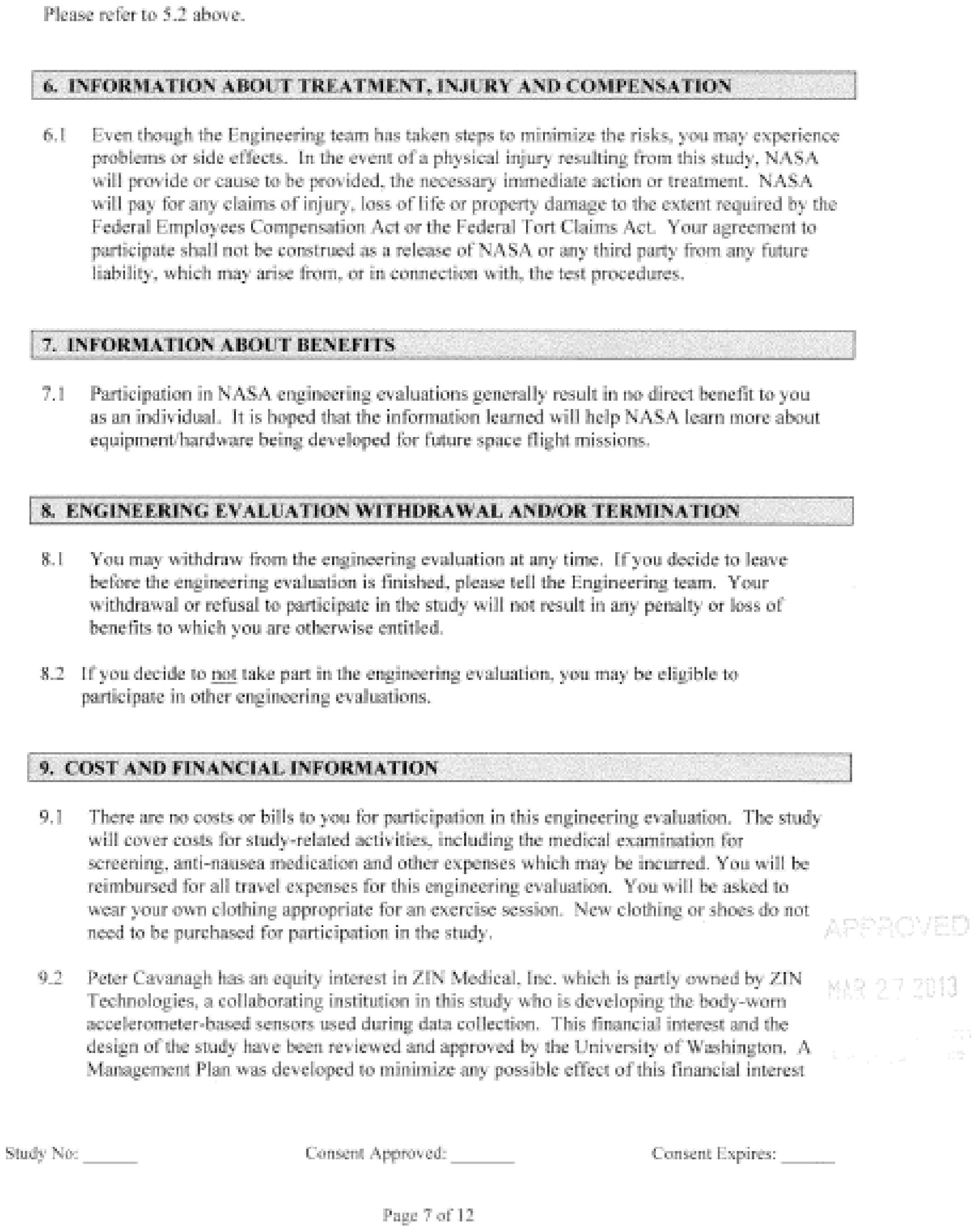
You may hit your head on the ceiling of aircraft during testing. You must be shorter than 70 inches in order to participate as a subject to prevent this from happening. The ceiling of the aircraft is also padded.

You may trip or fall while running on the treadmill or clothing could get caught in the exercise hardware (i.e. treadmill, cycle). Spotters will be close to you and will help if you trip or stumble. The testing area will be kept free of unnecessary cabling. You will wear spandex pants and shoelaces will be tucked inside the shoes. In addition, the hardware is equipped with an emergency stop (E-stop).

There is a risk that equipment failure or contact with sharp edges, corners or protrusions on equipment could result in subject injury. Test operators will perform a visual and sharp edge inspection before and during the flight on all equipment to be used. Should a sharp edge, corner or protrusion be found, it will be filed down or covered with foam padding, tape or other coverings to eliminate the hazard. Should any hardware failure arise during the test, further exercise will be stopped until the problem is resolved.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed. It is possible that co-workers will have access to your personal medical information. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. We may use the photographs and videotapes publicly in a journal or educational meeting. However, the images we will use cannot identify you. All photographs and video recordings will be digitally edited to remove personal identifiers. More information on confidentiality is provided below.

5.3 You are told that the hazards and the steps used to minimize the hazards include:



Please refer to 5.2 above.

6. INFORMATION ABOUT TREATMENT, INJURY AND COMPENSATION

6.1 Even though the Engineering team has taken steps to minimize the risks, you may experience problems or side effects. In the event of a physical injury resulting from this study, NASA will provide or cause to be provided, the necessary immediate action or treatment. NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. Your agreement to participate shall not be construed as a release of NASA or any third party from any future liability, which may arise from, or in connection with, the test procedures.

7. INFORMATION ABOUT BENEFITS

7.1 Participation in NASA engineering evaluations generally result in no direct benefit to you as an individual. It is hoped that the information learned will help NASA learn more about equipment/hardware being developed for future space flight missions.

8. ENGINEERING EVALUATION WITHDRAWAL AND/OR TERMINATION

8.1 You may withdraw from the engineering evaluation at any time. If you decide to leave before the engineering evaluation is finished, please tell the Engineering team. Your withdrawal or refusal to participate in the study will not result in any penalty or loss of benefits to which you are otherwise entitled.

8.2 If you decide to <u>not</u> take part in the engineering evaluation, you may be eligible to participate in other engineering evaluations.

9. COST AND FINANCIAL INFORMATION

9.1 There are no costs or bills to you for participation in this engineering evaluation. The study will cover costs for study-related activities, including the medical examination for screening, anti-nausea medication and other expenses which may be incurred. You will be reimbursed for all travel expenses for this engineering evaluation. You will be asked to wear your own clothing appropriate for an exercise session. New clothing or shoes do not need to be purchased for participation in the study.

9.2 Peter Cavanagh has an equity interest in ZIN Medical, Inc. which is partly owned by ZIN Technologies, a collaborating institution in this study who is developing the body-worn accelerometer-based sensors used during data collection. This financial interest and the design of the study have been reviewed and approved by the University of Washington. A Management Plan was developed to minimize any possible effect of this financial interest

Study No: ______ Consent Approved: _______ Consent Expires: ______

on your safety or welfare. The Plan will also protect the quality and reliability of the research.

10. PAYMENT AND REIMBURSEMENT

10.1 You will be paid to participate in the engineering evaluation as follows:

____$0____ is the total dollar amount for the study, including pro-rating (if you do not complete the study or if there is a bonus payment at the end of the study).

____X____ no payment if you are a NASA or other federal civil servant employee, contractor, or International Partner crewmember participating in the engineering evaluation.

11. SUBJECT RECORD CONFIDENTIALITY AND AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION (PHI)

11.1 Your protected health information may be used or shared with others during the engineering evaluation and may include:

- Existing medical records;
- Video and photographic materials;
- New information created from study-related tests, procedures, visits, and/or questionnaires.

11.2 Policies require that we put information about this research into your permanent medical record. If you do not have a medical record where your physical exam screening takes place, one will be created for you even if your only connection with them is as a research subject.

Information that will be put into your medical record

1. Your name, address, telephone number, date of birth, social security number, health insurance information, billing information, and any other information you provide on the hospital or clinic information form.

2. Information about this research study:
   - Name of the study, described as: Activity Monitoring during Parabolic Flight
   - Name of the organization or company that is paying for the research
   - The number the organization or company assigned to this study
   - The name of the researcher
   - The name of the study coordinator
   - Contact phone number for the study
   - Contact email address for the study
   - Emergency phone number for the study
   - Expected start and end dates for your time in the study
   - Whether there are healthy volunteers in the study

3. Information about these research procedures and test results:

- All information from your modified Air Force Class III physical exam

Who will have access

This medical record will be permanent. It will be stored with all other UW Medicine or NASA Medical Services medical records. A copy of your record may also be stored on the secure UW Medicine medical record computer system. Access to medical records and the computer system is restricted to only authorized staff with passwords for the system. Only authorized staff and people who have legal access to your medical record will be able to see it. This may include your insurance company and government regulatory agencies. If you have already given permission to anyone (such as your health insurance company) to look at your medical record, they may receive this research information if they ask for a copy of your medical record.

11.3 In an effort to maintain the confidentiality of private medical information, access to medical records will be limited as much as possible. Records will only be obtained when a physician is not able to confirm passage of the required physical examination. However, because records may need to be accessed, there is the possibility that this information will be seen by colleagues.

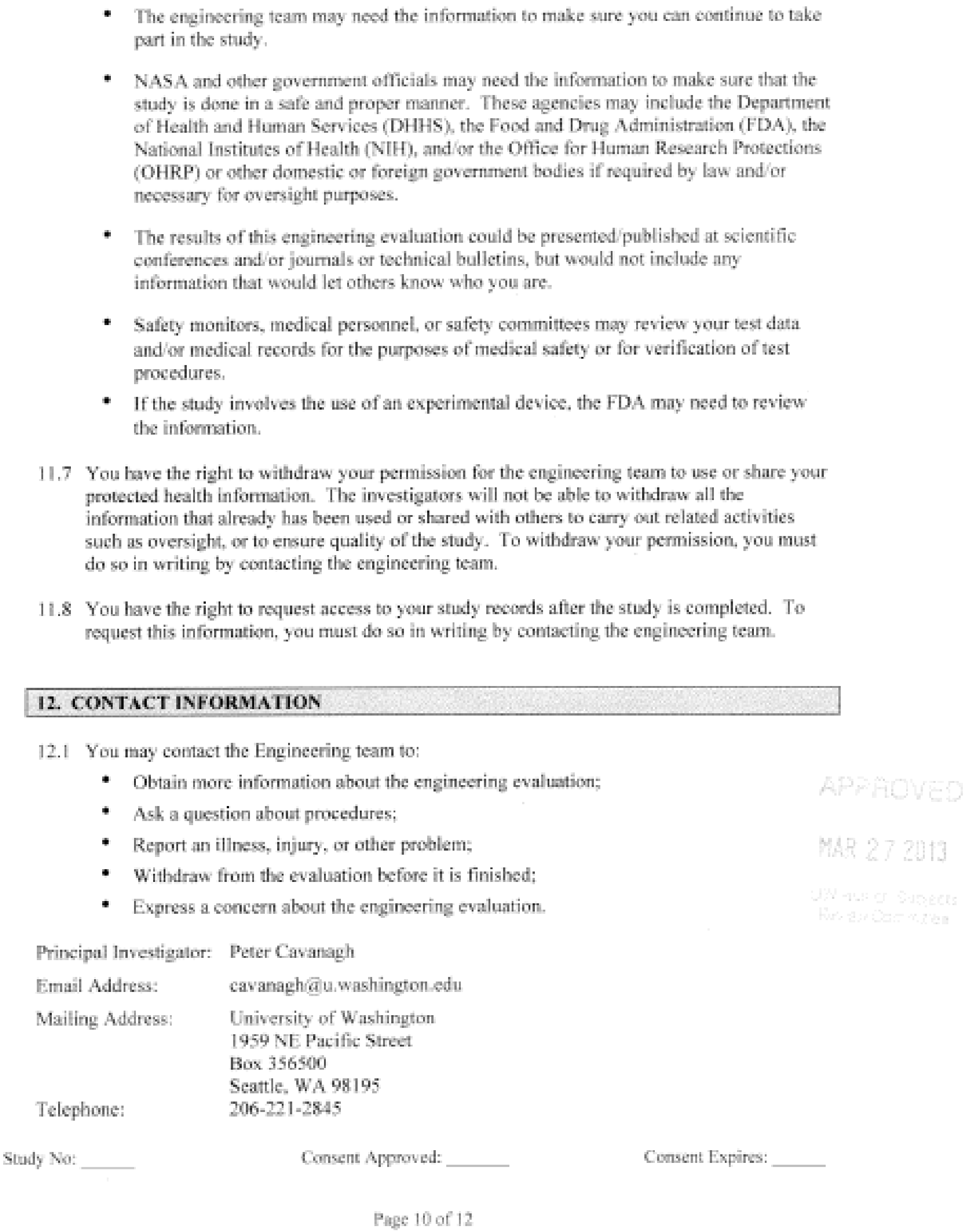
11.4 You may not need a medical examination for this study if you have had one recently. If this is the case, you will need to sign a separate release form for us to access your medical records to determine eligibility.

11.5 Your protected information may be used or shared by NASA offices of research oversight or quality assurance, medical monitors, and with others for the reasons below:

- To conduct and oversee the engineering evaluation;
- To make sure the testing meets NASA requirements;
- To conduct monitoring activities (including situations where you or others may be at risk or harm or reporting of adverse events);
- To become part of your medical record, if necessary, for your medical care;
- To review the safety of the engineering evaluation.

11.6 Every effort will be made to maintain the confidentiality of your engineering evaluation records. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. We will label your study information with a number, not your name. We will keep your name, address, telephone number, and other information that might identify you separate from your study information. The link to your private health information will be destroyed two years after the full study is completed or by December 31, 2014, whichever occurs first. There are many reasons why information about you may be used or seen by the others during or after this study. Examples include:

- If physiologic data (including but not limited to physiological measurements) are obtained from you for this study, they will become the property of NASA's Life Science Data Archive. The specimens or data may be used in this engineering evaluation, may be used in other studies, and may be shared with other organizations. All federal regulations concerning the privacy and confidentiality of these data will be followed. Records stored in this archive will not include names, registration numbers, or other information that is likely to link the information to you.



- The engineering team may need the information to make sure you can continue to take part in the study.
- NASA and other government officials may need the information to make sure that the study is done in a safe and proper manner. These agencies may include the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and/or the Office for Human Research Protections (OHRP) or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- The results of this engineering evaluation could be presented/published at scientific conferences and/or journals or technical bulletins, but would not include any information that would let others know who you are.
- Safety monitors, medical personnel, or safety committees may review your test data and/or medical records for the purposes of medical safety or for verification of test procedures.
- If the study involves the use of an experimental device, the FDA may need to review the information.

11.7 You have the right to withdraw your permission for the engineering team to use or share your protected health information. The investigators will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the engineering team.

11.8 You have the right to request access to your study records after the study is completed. To request this information, you must do so in writing by contacting the engineering team.

12. CONTACT INFORMATION

12.1 You may contact the Engineering team to:

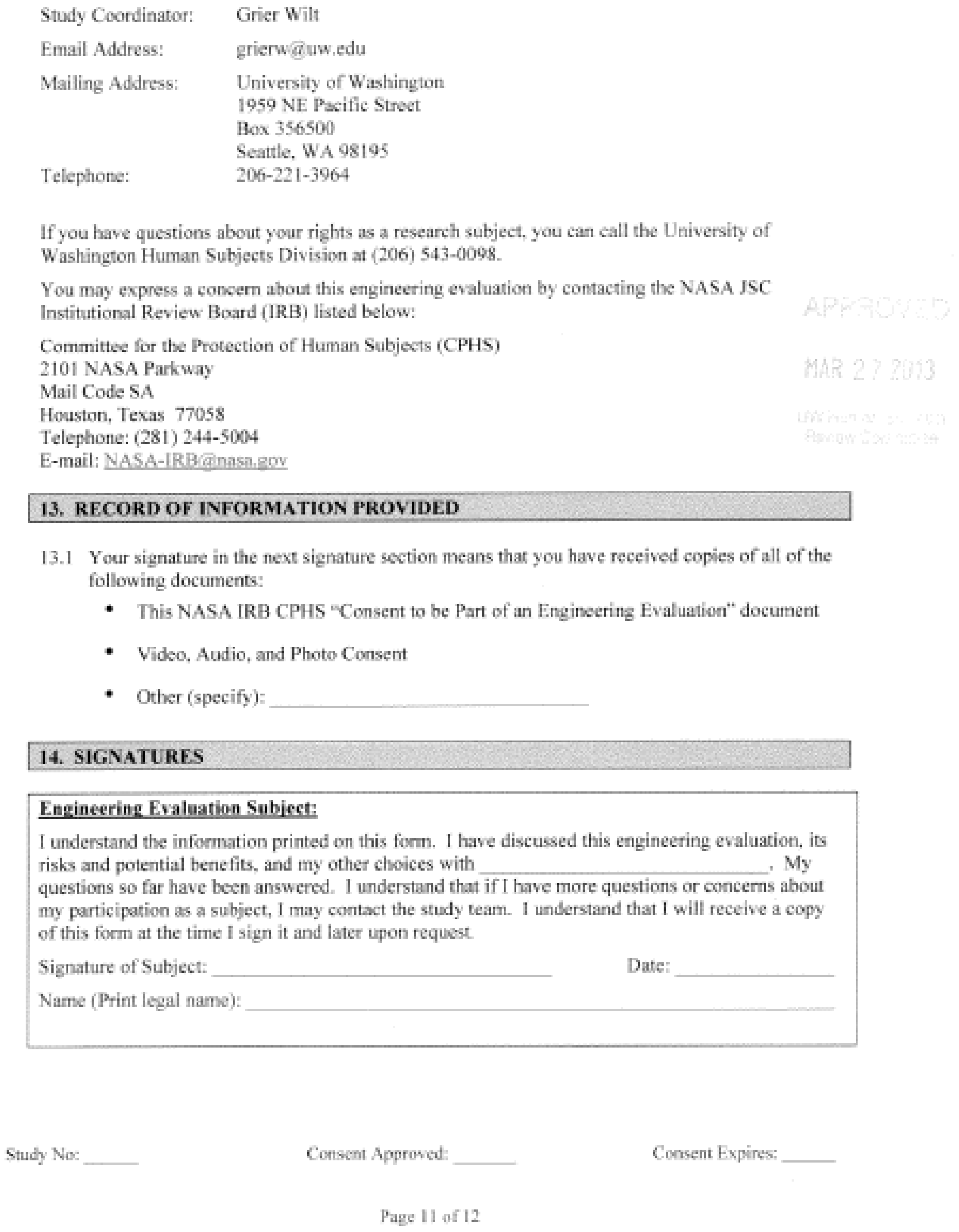
- Obtain more information about the engineering evaluation;
- Ask a question about procedures;
- Report an illness, injury, or other problem;
- Withdraw from the evaluation before it is finished;
- Express a concern about the engineering evaluation.

Principal Investigator: Peter Cavanagh

Email Address: cavanagh@u.washington.edu

Mailing Address: University of Washington
1959 NE Pacific Street
Box 356500
Seattle, WA 98195

Telephone: 206-221-2845



Study Coordinator: Grier Wilt

Email Address: grierw@uw.edu

Mailing Address:
University of Washington
1959 NE Pacific Street
Box 356500
Seattle, WA 98195

Telephone: 206-221-3964

If you have questions about your rights as a research subject, you can call the University of Washington Human Subjects Division at (206) 543-0098.

You may express a concern about this engineering evaluation by contacting the NASA JSC Institutional Review Board (IRB) listed below:

Committee for the Protection of Human Subjects (CPHS)
2101 NASA Parkway
Mail Code SA
Houston, Texas 77058
Telephone: (281) 244-5004
E-mail: NASA-IRB@nasa.gov

APPROVED
MAR 27 2013
UW Human Subjects
Review Committee

13. RECORD OF INFORMATION PROVIDED

13.1 Your signature in the next signature section means that you have received copies of all of the following documents:

- This NASA IRB CPHS "Consent to be Part of an Engineering Evaluation" document
- Video, Audio, and Photo Consent
- Other (specify): ______________________________

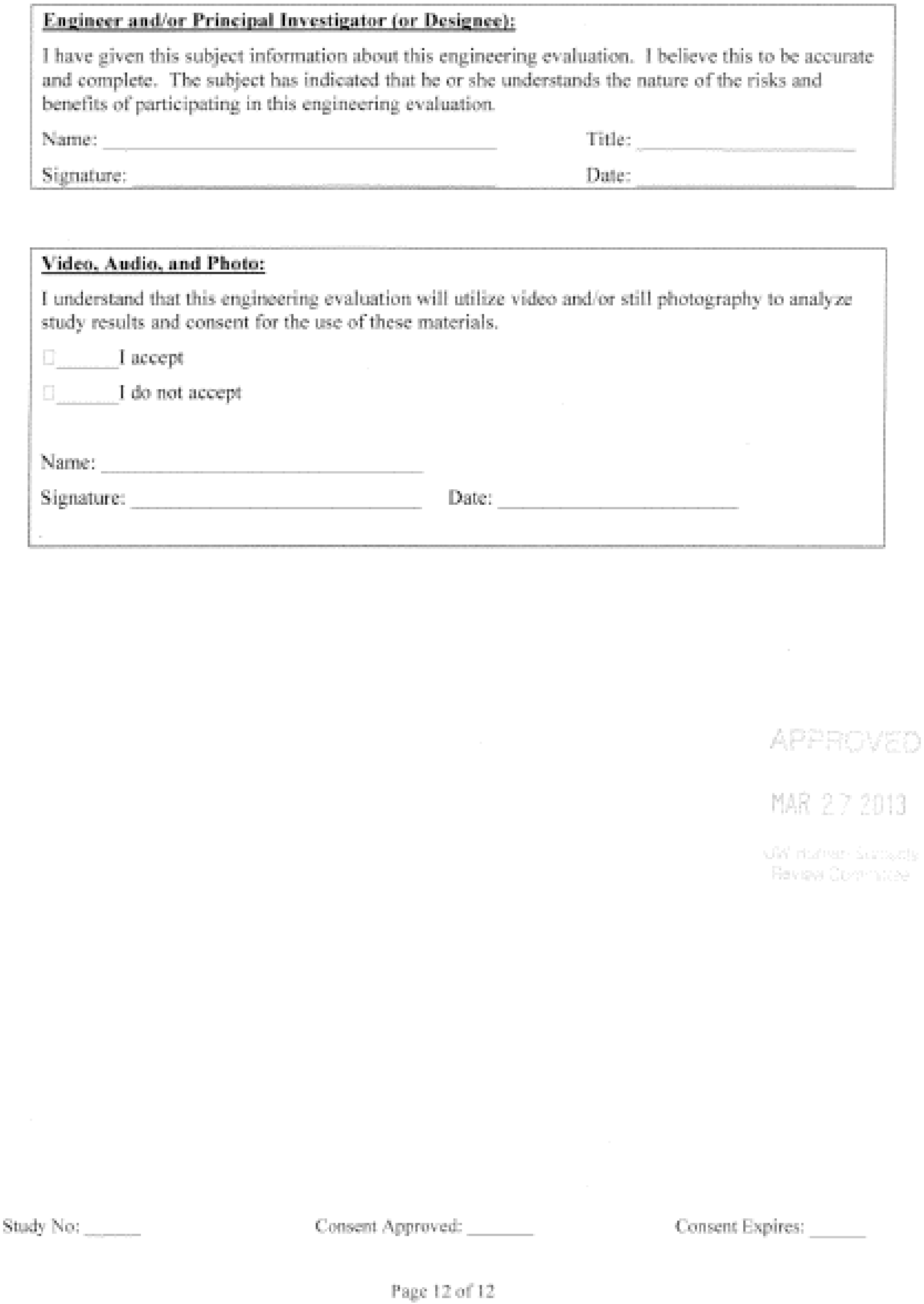
14. SIGNATURES

Engineering Evaluation Subject:

I understand the information printed on this form. I have discussed this engineering evaluation, its risks and potential benefits, and my other choices with ______________________________. My questions so far have been answered. I understand that if I have more questions or concerns about my participation as a subject, I may contact the study team. I understand that I will receive a copy of this form at the time I sign it and later upon request.

Signature of Subject: ______________________________ Date: ______________

Name (Print legal name): ____



Engineer and/or Principal Investigator (or Designee):

I have given this subject information about this engineering evaluation. I believe this to be accurate and complete. The subject has indicated that he or she understands the nature of the risks and benefits of participating in this engineering evaluation.

Name: ______________________ Title: ______________

Signature: ______________________ Date: ______________

Video, Audio, and Photo:

I understand that this engineering evaluation will utilize video and/or still photography to analyze study results and consent for the use of these materials.

☐______I accept

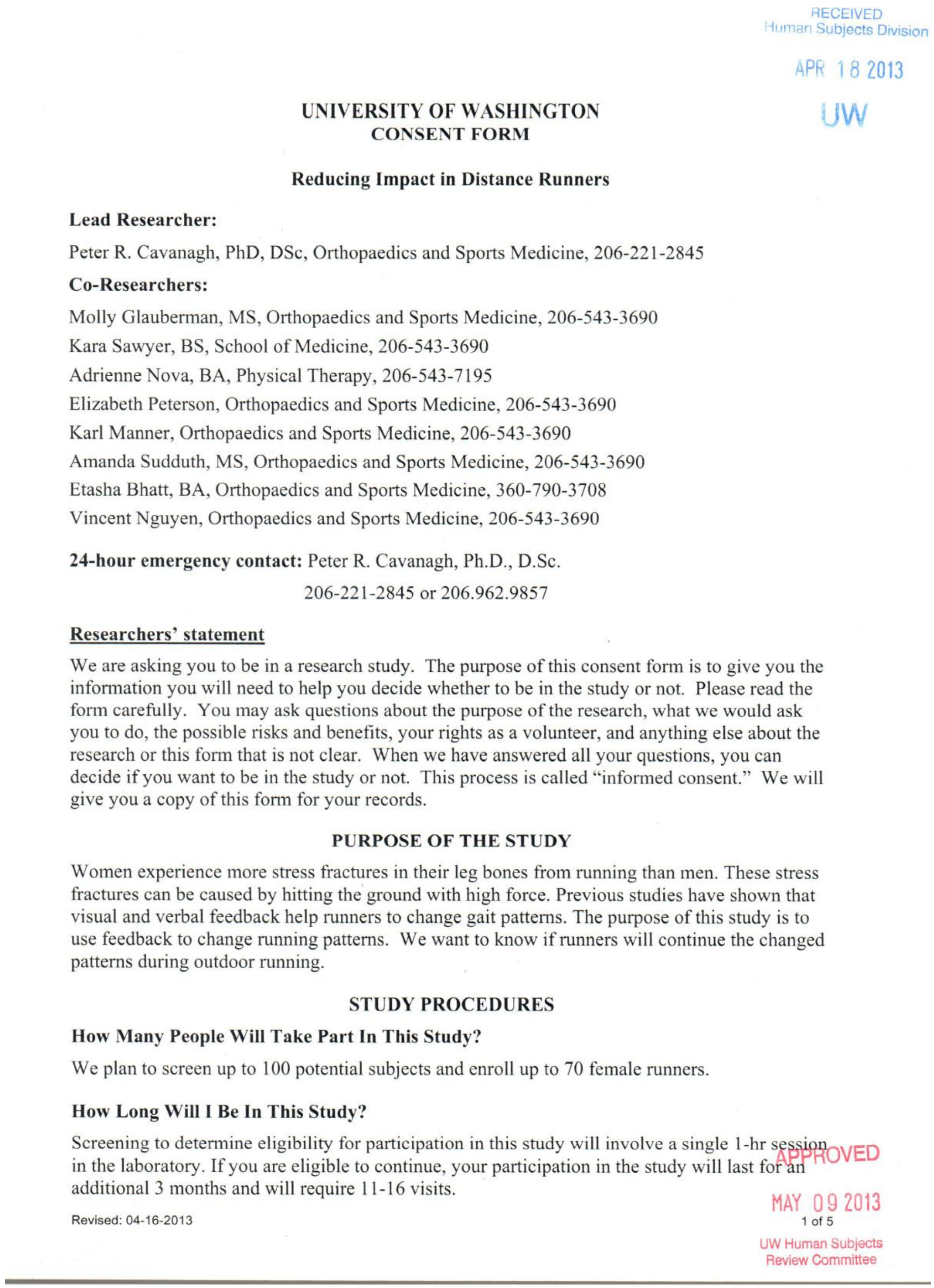
☐______I do not accept

Name: ______________________

Signature: ______________________ Date: ______________

Study No: ______ Consent Approved: _______ Consent Expires: ______

APPENDIX C: 1G SUBJECT CONSENT FORM



RECEIVED
Human Subjects Division
APR 18 2013
UW

UNIVERSITY OF WASHINGTON
CONSENT FORM

Reducing Impact in Distance Runners

Lead Researcher:

Peter R. Cavanagh, PhD, DSc, Orthopaedics and Sports Medicine, 206-221-2845

Co-Researchers:

Molly Glauberman, MS, Orthopaedics and Sports Medicine, 206-543-3690
Kara Sawyer, BS, School of Medicine, 206-543-3690
Adrienne Nova, BA, Physical Therapy, 206-543-7195
Elizabeth Peterson, Orthopaedics and Sports Medicine, 206-543-3690
Karl Manner, Orthopaedics and Sports Medicine, 206-543-3690
Amanda Sudduth, MS, Orthopaedics and Sports Medicine, 206-543-3690
Etasha Bhatt, BA, Orthopaedics and Sports Medicine, 360-790-3708
Vincent Nguyen, Orthopaedics and Sports Medicine, 206-543-3690

24-hour emergency contact: Peter R. Cavanagh, Ph.D., D.Sc.
206-221-2845 or 206.962.9857

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Women experience more stress fractures in their leg bones from running than men. These stress fractures can be caused by hitting the ground with high force. Previous studies have shown that visual and verbal feedback help runners to change gait patterns. The purpose of this study is to use feedback to change running patterns. We want to know if runners will continue the changed patterns during outdoor running.

STUDY PROCEDURES

How Many People Will Take Part In This Study?

We plan to screen up to 100 potential subjects and enroll up to 70 female runners.

How Long Will I Be In This Study?

Screening to determine eligibility for participation in this study will involve a single 1-hr session in the laboratory. If you are eligible to continue, your participation in the study will last for an additional 3 months and will require 11-16 visits.

APPROVED
MAY 09 2013
UW Human Subjects
Review Committee

What Is Involved In This Study?

The screening stage of this study will involve:

- 1-hr indoor screening session

If after screening you are eligible to participate in the training portion of the study it will involve eleven to sixteen additional 1-hr sessions:

- 1 - outdoor pre-training session
- 8 – laboratory-based training sessions
- 2 - outdoor post-training sessions
- 3 – optional laboratory-based training sessions
- 2 – optional outdoor post-training sessions

Screening Phase

The screening visit will take place at the University of Washington Department of Orthopaedics and Sports Medicine Research Lab. You should wear your typical running clothes and running shoes. We will ask you to fill out an intake form. The form will ask about your current state of health (i.e. pregnant, mental health status, recent weight loss/gain), a review of systems (i.e. asthma, heart problems, arthritis) and your running experience (i.e. years running, volume, injury history). Your answers to these questions are voluntary.

You will then be asked to perform a simple range-of-motion test. This test involves non-invasive measurements of your knee joint angle during different activities. Finally you will be asked to briefly run on a treadmill in order to assess your running characteristics. The length of this run will not exceed 15 minutes and you will be able to set the pace yourself.

This will conclude the screening phase of the study.

Training Phase

If you qualify to participate in the study, we will ask you to come for additional training sessions. We will ask you to fill out the intake that you filled out at the screening session at each training session.

We will ask you to keep a training log throughout your participation in this study. We will provide you with the training log.

During the Training Phase, a non-invasive shoe- or ankle-mounted device will be used to measure running characteristics. We will provide you with running shoes to use for the duration of the study if a shoe-mounted device is used. You will use your own running shoes when the device is ankle-mounted. At all sessions you should wear your typical running clothes.

Outdoor pre-training session
For this visit you will run a short pre-set circuit at your normal training pace. A non-invasive shoe- or ankle-mounted device will be used to measure running characteristics during this circuit. Your running will not exceed 30 minutes.

Laboratory-based training sessions

There will be 8 laboratory-based training sessions. These 1-hr visits will take place at the University of Washington Department of Orthopaedics and Sports Medicine Research Lab. They will involve running on a treadmill while receiving visual and/or verbal feedback. The first 6 visits will occur over 3 consecutive weeks with 2 sessions per week. Sessions will be separated by at least 1 day. The remaining two training sessions will be conducted at least one week apart.

We would like to photograph and video-record the sessions to have an accurate record. We will tape reflective motion sensors onto your skin so the video can pick up movement patterns. We will use the images to understand how training affects running patterns. When we use the photographs and video recordings outside of the study team, we will digitally edit the images to not identify you. Please indicate below whether or not you give your permission to be photographed and video-recorded.

Outdoor post-training sessions

There will be two outdoor post-training sessions. The first session will occur 1 month after your last lab-based training session. The final outdoor session will occur 1-month after that. We will ask you to run a short pre-set circuit at your normal training pace. A non-invasive shoe- or ankle-mounted device will be used to measure running characteristics during this circuit. Your running will not exceed 30 minutes.

Optional training sessions

Depending on the results of the outdoor post-training sessions, three additional laboratory-based sessions may be offered to you. Each 1-hour training session will involve running on a treadmill while receiving visual and/or verbal feedback. Once the laboratory training sessions are completed, the two outdoor post-training sessions will be repeated.

This will conclude your involvement in this study.

Visit Schedule

Session #	Location	Involved in Session	Length of Session
1 Screening	UWMC Orthopedics and Sports Medicine Laboratory	- intake form - range of motion test - treadmill running	1 hr
2 Pre-training	Outdoor location TBD	- intake form - outdoor running circuit	1 hr
3 - 10 Training	UWMC Orthopedics and Sports Medicine Laboratory	- intake form - treadmill running - review of training diary	1 hr
11, 12 Post-training	Outdoor location TBD	- intake form - outdoor running circuit - review of training diary	1 hr
13, 14, 15 Training Review	UWMC Orthopedics and Sports Medicine Laboratory	- intake form - treadmill running - review of training diary	1 hr
16, 17 Post-training	Outdoor location TBD	- intake form - outdoor running circuit - review of training diary	1 hr

RISKS, STRESS, OR DISCOMFORT

There are no known physical risks related to the sensors, as it will be inside the heel of your running shoe or taped to your ankle. Some people may experience irritation from the tape for the ankle-mounted sensors.

The use of reflective markers attached with tape for motion capture may cause skin irritation, which is usually minor and resolves quickly.

There is a small risk involved with treadmill running. The treadmill, like any commercial treadmill, includes handrails and an emergency stop button.

The physical risk for running is about the same as your normal running. Sessions will not exceed 30 minutes of running and you will choose your running pace. We will encourage you to stretch and warm up prior to testing.

We have addressed concerns about privacy in the OTHER INFORMATION section.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You can obtain information about healthy running by contacting your physician or a physical therapist. They may be able to discuss training programs appropriate for your needs and level of fitness.

BENEFITS OF THE STUDY

There is a potential that the training you receive as part of your participation in this study could lead to a reduction in the risk of injury during running.

OTHER INFORMATION

Voluntary Participation:

Taking part in this study is completely voluntary. You can choose not to participate, or stop participating at any time, by notifying the investigator. To withdraw your study information contact the lead researcher:

Dr. Peter Cavanagh
Dept. of Orthopaedics and Sports Medicine
Box 356500
University of Washington
Seattle, WA, 98195-6500

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

Privacy and Confidentiality:

The researchers will keep the study information confidential. We will label your research information with a study number, not your name. We will keep your name, address, telephone number, and other information that might identify you separate from the research information in a secure location. We will destroy any link between the study information and your identity by January 31, 2016. If you are not eligible to participate in the full study after screening, we will still keep your study information but will destroy any link between the study information and your identity after all subjects have been enrolled, on or about January 31, 2015.

We may use the photographs and videotapes publicly in a journal or educational meeting. However, the images we will use cannot identify you. All photographs and video recordings will be digitally edited to remove personal identifiers.

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities. If you provide your email address as a form of contact, please note that we cannot guarantee the confidentiality of email communications.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

Cost and Payment:

There is no cost to you. You will not be paid for being in this study. You will be given a voucher for parking for your laboratory-based training sessions if you need it.

COMPENSATION FOR INJURY

If you think you have an injury or illness related to this study, contact the study staff [Peter Cavanagh at 206-221-2845] immediately. They will treat you or refer you for treatment.

If you suffer a physical injury as a direct result of being in this study, we will provide treatment to you. The University of Washington will pay up to $10,000 to reimburse you for treatment of injury or illness resulting from the study. No money has been set aside to pay for things like lost wages, lost time, or pain. However, you do not waive any rights by signing this consent form.

Printed name of study staff obtaining consent Signature Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

I ☐ agree ☐ do not agree for the researchers to photograph or video record the study sessions as described above in this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher
Subject

APPROVED
MAY 09 2013
UW Human Subjects
Review Committee

Revised: 04-16-2013