CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH

HUMAN BODY SELF-ROTATIONS IN SIMULATED MICRO-GRAVITY

You are asked to participate in a research study conducted by Pierre Bertrand, B.S., and Professor Jeffrey Hoffman, PhD from the Aeronautics and Astronautics department at the Massachusetts Institute of Technology (M.I.T.). You have been asked to participate in this study because you have been identified as a member of the M.I.T. community who might be interested in such research program. If you agree to take part of this study, you will be one of about 10 to 20 other subjects. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

- **PARTICIPATION AND WITHDRAWAL**

Your participation in this research is completely VOLUNTARY. If you choose to participate you may subsequently withdraw from the study at any time without penalty or consequences of any kind. If you choose not to participate, that will not affect your relationship with M.I.T. or your right to health care or other services to which you are otherwise entitled. The investigators may withdraw you from this research if circumstances arise which warrant doing so. If at any time during the study, any investigator feels that your safety is at risk, the investigators may terminate your participation in this study.

- **PURPOSE OF THE STUDY**

The purpose of this study is to identify the control strategies used by humans to move their body from one location to another in the absence of gravity. Future space exploration missions will require astronauts to spend long periods of time in a microgravity environment and then be expected to perform tasks in full or partial gravity. Understanding the mechanisms by which humans adapt their control strategies to differing gravity environments may lead to the development of new astronaut countermeasures. These countermeasures would be designed to accelerate astronauts' adaptation to a new gravity environment and reduce the risk of injuries associated with falls.

- **PROCEDURES**

If you volunteer to participate in this study, we would ask you to do the following things:

Preparation:

- You will first be ask to fill questionnaire about your athletics history and general information.
- You will perform balance motor control tasks (jump rope and beam tasks). You will be able to train for each task with 3 trials before being evaluated, making sure that you are proficient at these tasks, and that these tasks are safe for you. The description of the two balance motor control tasks are described below:

    - **jump rope task:** subject are asked to perform a basic jump for the first 90s, and then for the last 30s they were to alternate between a basic jump and a crisscross jump. In the basic jump, both feet are slightly apart and the subject jumps over the rope as it passes under him/her. The crisscross method is similar to the basic jump except that the left hand goes to the right of the body and right hand goes to the left of the body.
    - **beam task:** the subject is to 1) walk to the end of the beam; 2) perform a half-turn; 3) walk to the half-way point of the beam; 4) perform a small jump; and 5) walk to the end of the beam

During the training of the beam task, you will be assisted, to make sure that the task is safe for you and there is a minimum risk of fall.

Experiment:

You will be in a climbing harness, strapped in and lifted a few inches off the ground such that you cannot reach the floor with your feet.

- You will be instructed where the cameras are that will be recording your position
- You will be given the opportunity to make yourself comfortable in each harness before the experiment begins.
- You will be asked to reorient your body around your three body axes in a clockwise and counterclockwise manner.
- Each type of rotation will be repeated approximately 5–10 times.

The experiment will take place in the DuPont M.I.T. gymnastic room. The entire experiment will take approximately 2 hours to complete.

- **POTENTIAL RISKS AND DISCOMFORTS**

There is a minimal risk from participation in this experiment. Safety precautions will always be the primary consideration. As you will be suspended through a body-harness,

to prevent any fall, you may feel minor discomfort. It is expected to be minimal and have no long-term effects. Please let the investigators know if it is the case and the trial or session will be terminated. The risk of a fall from the harness is minimal but gymnastic landing mattresses will be positioned under the suspension device in order to prevent any harmful fall. The body harness restricts other contact with the structure of the suspension system. Similarly, during the beam tasks, the experimenter will help you to gain confidence in the task, while gymnastic landing mattresses will be positioned under the beam in order to prevent any harmful fall.

You will be inspected immediately before and after test sessions. As minor risks associated with this study are all immediately evident, these inspections should suffice. You will contact the MIT Medical Department as well as the test director immediately if any prolonged pain occurs.
The treatment or procedure may involve risks that are currently unforeseeable.

- **ANTICIPATED BENEFITS TO SUBJECTS**

There are no known benefits to the individual subject for participation in this study.

- **ALTERNATIVES TO PARTICIPATION**

An alternative is not to participate in the study.

- **PAYMENT FOR PARTICIPATION**

Subjects will NOT be paid for participating in this study.

- **FINANCIAL OBLIGATION**

There is no financial obligation of the subject.

- **PRIVACY AND CONFIDENTIALITY**

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research will be disclosed to others without your written permission, except: if necessary to protect your rights or welfare, or if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be

protected or disguised. The results from your participation will be identified by a randomly generated numerical code. These results will be stored on a secure server and a back-up hard drive and secured in a locked office of the Man Vehicle Lab. When the data analysis and study are complete, the results will be filled in the archive of the server, and in the office of the Principle Investigator. The results will always remain anonymous, and always referred to by the numerical code.

• WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If you experience any of the following side effects: severe pain, skin reaction, or other issue, or if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Pierre Bertrand, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

- **NEW FINDINGS**

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, which might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

- **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

- **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact:

Principal Investigator	Professor Jeffrey Hoffman jhoffma1@mit.edu 617-452-2353
Co-Investigator	Pierre Bertrand pjbertra@mit.edu 857-253-9911

- **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Subject

_____
Name of Legal Representative (if applicable)

_____ _____
Signature of Subject or Legal Representative Date

SIGNATURE OF INVESTIGATOR

I have explained the research to the subject or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date (must be the same as subject's)

SIGNATURE OF WITNESS (If required by COUHES)

My signature as witness certified that the subject or his/her legal representative signed this consent form in my presence as his/her voluntary act and deed.

_____
Name of Witness

_____ _____