Informed Consent Document

A Prospective Study of Human Bone Adaptation Using a Novel in Vivo Loading Model

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Informed Consent Agreement for Participation in a Research Study

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Title of Research Study:
A Prospective Study of Human Bone Adaptation Using a Novel in-vivo Loading Model

Sponsor:
National Institutes of Health (NIH/NIAMS)

Introduction
You are being asked to participate in a research study. Before you agree, however, you must be fully informed about the purpose of the study, the procedures to be followed, and any benefits, risks or discomfort that you may experience as a result of your participation. This form presents information about the study so that you may make a fully informed decision regarding your participation.

Purpose of the study: This research is being done to better understand how forces you apply to your skeleton change and improve the strength of your bones. This information may help us in the future to identify specific types of exercises that can improve bone health and reduce the risk of osteoporosis later in life.

Procedures to be followed: This research will take place over a two-year period. Although the amount of time required to participate is small, about five minutes or less each day, long-term commitment and consistency is important for us to collect the highest quality data possible. If you agree to participate in this research study, you agree that you will do your best to adhere to the study protocol.

This research will be performed at Worcester Polytechnic Institute (WPI), at the UMass Memorial Medical Center, and at your home.

1. The Musculoskeletal Biomechanics Laboratory at 60 Prescott St. Worcester, MA
2. The UMass Memorial Medical Center (for a bone density scan).
3. Quest Patient Service Center at 338 Plantation St. Worcester, MA (for a blood draw).

SCREENING:

Before you are assigned to a group in the research study we will measure your bone density, blood vitamin D levels, and estrogen levels to determine whether you are eligible to participate in the research study.

To test bone density we use a machine called a DEXA. This is a special type of x-ray and is located in the UMass Memorial Medical Center. You will be given a urine pregnancy test to self-administer before receiving the DEXA and we will cover your torso with a lead apron to protect you from the x-rays. A research team member will read the results of the test. You will be able to see the results of the DEXA and will be given a copy.

Next, you will have one tube of blood drawn at the Quest Patient Service Center. A research team member will accompany you. This blood will be sent to a laboratory to measure your levels of vitamin D, estrogen, and some hormone levels. The test takes a few days and we will contact you as soon as your results are available.

If your levels fall into a normal range, you will be eligible to participate in the research study. If you do not fall into a normal range, you will not be eligible to participate in the research study. If this is the case, a study team member will explain your results to you, and you may wish to discuss them with your doctor. You will be given a copy of your test results.

If you qualify to participate you will be asked to return for your first study visit. During this visit you will be randomly assigned to one of three groups. Your group assignment will be determined by drawing a sealed envelope. You may be assigned to one of three possible groups:

1. Control group
2. "Low" experimental group
3. "High" experimental group

If you are assigned to the control group then you will not participate in any intervention, but we will still collect data at regular time intervals. If you are in this group, you may continue your regular activities.

If you are assigned to one of the experimental groups then you will be participating in a mechanical loading intervention that involves voluntary leaning onto the palm of your non-dominant hand. For right-handed people this means you will be applying a force to your left hand.

Whether you are assigned to the control or experimental groups, we will need to contact you for scheduling appointments and follow-up. Please circle the best way for us to get in touch with you below:

EMAIL TEXTING TELEPHONE
Number/address:_____

LOADING INTERVENTION:

If you are assigned to an experimental group you will be asked to apply a force around half your body weight to the palm of your non-dominant hand up to 100 cycles per day, 4 times per week. Each day that you do this it will take about four minutes to complete. The exact amount of force will be assigned based on your group assignment and your individual anatomy.

You will be given three items to take home with you. We will explain and demonstrate how to use each of the items when they are given to you. We will also include written instructions and a phone number that you can call if you have any questions. These items will help you to perform the loading intervention correctly and will help us to track your progress:

1. A voice recorder with sound cues. This will "beep" 100 times and you should lean onto your hand each time you hear a beep.
2. A portable wrist loading device. This device contains an electronic scale connected to a tiny data recorder that reads the amount of force on the scale. It also has lights on it that light up when you push on it with the right amount of force.
3. A log book that you will initial each time you complete a set of 100 loading cycles.

If you participate in the loading intervention, a study team member will be in regular contact with you, especially during the first few weeks. At least every month someone will contact you to ask about how the loading is going, about whether you are feeling any pain or having difficulty doing the loading, and will address any concerns that you have. Depending on your preference, we will contact you either through email, text messaging, or by telephone. If you are having problems with the loading or are experiencing pain, we may temporarily decrease the amount of force or the number of times per week that you apply the load to your hand.

No matter what group you are assigned to, you will receive a "bone health tip of the week" either by text or by email. The purpose of these tips is to help you become better informed about your own bone health.

DATA COLLECTION:

Whether you are in the control group or an experimental group, you will need to come to the study site 7 times over the next 24 months. These visits will occur every 3 months for the first year (at month 0, 3, 6, 9, and 12), and every 6 months for the second year (at months 18 and 24).

During your first and fifth study visit you will have a clinical CT ("cat") scan of both forearms at UMass Memorial Medical Center.

1. You will check in at the Diagnostic Radiology desk. A member of our research team will meet you in the waiting area or may drive you over from the laboratory.

2. When your name is called, you and the research team member will walk back to the CT scanner. You will be given a pregnancy test to self-administer before any testing occurs. If you are pregnant you will be asked to withdraw from the study because it is not safe for your baby to be exposed to radiation from the CT scanner.
3. The Radiology Technician will have you lay on the bed of the CT scanner with your arm stretched out above your head. We will place your wrist in a brace and we will place a small plastic block called a phantom underneath your forearm.
4. The technician will put a lead apron over your stomach and upper legs to protect you from radiation exposure.
5. The CT scan itself only takes a few minutes. During this process the scan bed moves back and forth.

During the first study visit and every other study visit, you will go to the WPI laboratory. Each laboratory visit will take approximately one (1) hour.

- You will fill out or update four (4) physical activity surveys.
- We will ask you about any medical events that can affect your bone such as pregnancy, a change in birth control methods, and any vitamins, supplements, and prescription drugs you are currently taking.
- We will measure/update your height, weight, and wrist circumference.
- If you are assigned to an experimental group you will be asked to bring your log book, portable wrist loading device, and voice recorder with you for each study visit. In the laboratory we will check your log book and collect data from the portable device. We will provide new batteries for the voice recorder.
- We will use a high-resolution "cat" (CT) scanner to examine a small region of each of your forearms in detail.
    - You will put your arm in a brace to hold it still
    - Your arm will be inserted into a small hole in the side of the machine
    - We will cover your torso with a lead apron
    - The scan takes 3 minutes to complete, during which you will need to try not to move your arm
    - We will scan the other arm in the same manner

Risks to study participants: There is a risk of loss of confidentiality related to the collection of research data.

Risks associated with radiation:

As a result of participating in this study, you will receive up to 32 CT scans, 28 of which are high resolution scans. The amount of radiation you will be exposed to is very small. It is approximately equal to the amount of radiation each individual receives from natural sources to the whole body during a period of one month. Radiation is potentially harmful, but the risk, if any, of the radiation dose in this study is so small that it is difficult to measure. If you have had many x-rays or if you might be pregnant, you should discuss this with the investigator and your primary physician.

The current recommendations are that people should limit their voluntary exposure to radiation to 100 millirem per year. If you decide to participate in all 7 time points of this research study,

you could receive up to 44.45 millirem over a 2-year period.

Risks associated with blood draws:
You may feel slight discomfort from the needle stick for the blood draw. There is also a small chance of bruising, bleeding, fainting, lightheadedness, and infection at the site of the blood draw. To minimize these risks, blood will be drawn by an experienced nurse or phlebotomist.

Risks associated with the loading intervention:
The loading intervention requires that you load, or put pressure on your wrist. This may cause some initial discomfort, but this minor soreness is expected to respond to ibuprofen (Motrin, Advil) or acetaminophen (Tylenol) and be resolved over a short time. If you experience continued soreness you should contact an investigator. Rare but serious risks include the possibility of developing carpal tunnel syndrome or a stress fracture in your wrist due to the loading intervention. These conditions are usually preceded by prolonged wrist soreness, so to prevent against this possibility you should contact an investigator if you experience soreness for more than two weeks. At this time more than 50 women have participated in the loading intervention for up to 6 months at a time.
Within that group, five subjects experienced some temporary wrist soreness, and nobody experienced carpal tunnel syndrome or stress fractures.

If you are participating in any other research studies, or decide to participate in other studies, you should contact an investigator to let us know.

What are the reproductive risks?
Participating in this research involves risks to pregnant women and/ or an unborn baby that are currently unforeseeable. To protect against possible side effects of the radiation, if you are pregnant or nursing a child you may not take part in this study. If you are a woman of childbearing ability, you will be given a pregnancy test before you receive a CT.

Benefits to research participants and others: You may not directly benefit from participation in the research. The knowledge gained by this study will provide a further understating of the factors involved in maintaining a healthy level of bone mass.

Record keeping and confidentiality: The 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 (for example, if you are injured and need emergency care or when the Office for the Protection of Research Subjects monitors the research or consent process) or if required by law.

Study information which identifies you and the consent form signed by you will be looked at and/or copied for examining the research by

- The National Institutes of Health
- Office for the Protection of Research Subjects, State of Massachusetts Auditors

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside the research. All files that contain your name are kept in locked files or in a medical record maintained by UMass Memorial Medical Center. Once you have agreed to participate in the study, all data about you is coded with a subject number and not your name. The computers in which information is stored at WPI are password protected. 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 (for example, if you are injured and need emergency care or when the WPI Institutional Review Board monitors the research or consent process); 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. Five years after we have completed the data analysis from this research study we will destroy any identifying information from the data we collect. However, the information contained in the medical record at UMass Memorial Medical Center will be retained as required by law.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Karen Troy and her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes your name, telephone number, email address, list of medications that you are taking, and CT data.

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study;
- With law enforcement or other agencies, when required by law;
- With the sponsor/funding agency of the research, the National Institutes of Health, as required to conduct the research and if the research results need to be confirmed;
- With non-WPI collaborators of the research study: Thomas J. Schnitzer, MD, PhD
- With representatives of government agencies (i.e., Food and Drug Administration), review boards including the Worcester Polytechnic Institute Institutional Review Board, the University of Massachusetts Medical Center and its representatives, and other persons who watch over the safety, effectiveness, and conduct of research.

If all information that identifies you is removed from your health information, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

You will not have access to the health information related to this research study until the study is done. However, this information is available to your doctor in the case of an emergency. At the end of the study, you will again have access to health information that is normally within your medical records (treatment, insurance and billing information). However, the researcher may not give you access to the research records or information that is not usually kept in your medical record, as it is not required by HIPAA.

How will your health information be protected?

The researchers and the National Institutes of Health agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

Compensation or treatment in the event of injury: You may have medical problems or side effects from taking part in this research study. If you believe that you have become ill or been injured from taking part in this study, treatment may be obtained through:

- The UMass Memorial Medical Center OR
- Your regular doctor OR
- The treatment center or clinic of your choice.

If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors. You may contact the researcher Karen Troy at 508-831-6093 to talk to her about your illness or injury. You may also email the researcher at ktroy@wpi.edu or MBL@wpi.edu. In an emergency, you can contact Karen Troy at home at 508-340-4733.

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study. There are no plans for WPI or UMass Memorial Medical Center to provide free medical care or to pay for research-related illnesses or injuries, or for WPI or

UMass Memorial Medical Center to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

You do not give up any of your legal rights by signing this statement.

Cost/Payment: There are no costs to you for participating in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will receive $20 for each completed study visit. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive a total of $160.

If you are assigned to an experimental group:
For each 3-month interval during which you successfully complete at least 70% of your assigned loading bouts, you will receive an additional $25 in compensation. We will determine this based on data recorded in your loading device and logbooks.

Can I withdraw or be removed from the study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care at WPI.
You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the investigator may ask you to return any equipment given to you as part of the study.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests
- You were to object to any future changes that may be made in the study plan
- You experience a severe side effect
- You are no longer eligible to participate because of a change in your health status

In the event you withdraw or are asked to leave the study, you will still be compensated as described above.
Your Authorization for release of health information for this research study does not have an expiration date, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: Karen L. Troy, PhD
Dept. of Biomedical Engineering 100
Institute Road
Worcester, MA 01609

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the

integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Who should I contact if I have questions?

Contact the researchers Karen L. Troy, PhD, Assistant Professor at 508-831-6093 or email address: ktroy@wpi.edu OR MBL@wpi.edu .

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury (or a bad reaction to the study treatment), and/or
- if you have questions, concerns or complaints about the research.

For more information about this research or about the rights of research participants, or in case of research-related injury, contact: Karen Troy (contact information is on page 1). In addition, include the contact information for the IRB Chair (Professor Kent Rissmiller, Tel. 508-831-5019, Email: kjr@wpi.edu) and WPI's University Compliance Officer (Jon Bartelson, Tel. 508-831-5725, Email: jonb@wpi.edu).

Your participation in this research is voluntary. Your refusal to participate will not result in any penalty to you or any loss of benefits to which you may otherwise be entitled. You may decide to stop participating in the research at any time without penalty or loss of other benefits. The project investigators retain the right to cancel or postpone the experimental procedures at any time they see fit.

By signing below, you acknowledge that you have been informed about and consent to be a participant in the study described above. Make sure that your questions are answered to your satisfaction before signing. You are entitled to retain a copy of this consent agreement.

_____ Date: _____

Study Participant Signature

APPROVED
WPI IRB 1
9/20/16 to 7/14/17

_____

Study Participant Name (Please print)

_____ Date: _____

Signature of Person who explained this study