

Appendix C

University of Wisconsin-Madison

Do not write in this

Application for Initial Review of Research

Projects Involving Human Subjects

Health Sciences IRB • Health Sciences Minimal Risk
IRB

space

Protocol #

Date:

Training Checked ___

I. Application Cover Sheet

A. Researcher and Protocol Identification:

1. Protocol Title: Accessible Ergometer
2. Principal Investigator/Advisor
Name: Kreg Gruben
Job Title: Assistant Professor
Department/Unit Name: Kinesiology
Office Address: 1081 Gymnasium – Natatorium 2000 Observatory Drive Madison, WI 53706
Phone & Pager: (608) 262-2711
Fax: (608) 262-1656
Email: gruben@education.wisc.edu

B. Project Sponsorship Information (current or planned):

1. Is the research to be funded with federal funds, or are federal funds being applied for? Yes
 No
If so, please provide a copy of the grant proposal
2. Is the research to be funded by a private sponsor? Yes No
3. For each current or potential funding source, provide: John Enderle, Ph. D. University of Connecticut
 - a. The name of the sponsoring agency (include UW funding): (860) 486-5521
 - b. The UW proposal number or planned submission date
 - c. The UW grant fund and account number (i.e., 144-abxx)
 - d. The agency award number:

C. Additional Project Information:

1. Is this a clinical research project? (Definition: *Clinical Research Involving Human Subjects* means any research or medical procedure involving human subjects or the use of human samples for the development and evaluation of patient therapies, such as diagnostic tests, drug therapies, or medical devices. It includes clinical trials.) Yes No
2. Do any project personnel receive incentives for recruiting human subjects or for any other purpose directly related to the study? If any project personnel receive incentives for recruiting human subjects, this should be described fully in the Study Description section of this application. Yes No
3. Do any personnel involved in the design, conduct, or analysis of the study have any proprietary interests (royalties, patents, trademarks, copyrights, or licensing agreements) involving any agent, device, or software being evaluated as part of the study? Yes No
4. In addition to the sponsor(s) of this project, are other companies or business entities involved in or potentially affected in a significant way by this research project? Yes No
 If yes, list the names of those companies/business entities.
5. Is this investigator-initiated research? Yes No
6. Do you intend to use General Clinical Research Center (GCRC) facilities? Yes No

D. Other Approvals:

Final approval of the Health Sciences Human Subjects Committee may require review and/or approval by another committee representing the University, its affiliates, a department, or a section. Please submit a notice of review and/or approval by any of the following entities. If review is pending, please indicate the date on which it will occur.

Committee	Phone	Review Required?	Review Date
University of Wisconsin Comprehensive Cancer Center Clinical Affairs Committee <i>Reviews all cancer-related research protocols.</i>	263-0169	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Cardiology Clinical Research Committee <i>Reviews all Cardiology Section research protocols and provides consultation if needed on cardiac issues for protocols originating elsewhere.</i>	263-4856	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Institutional Biosafety Committee / Office of Biological Safety <i>Reviews the research use of recombinant DNA and its derivatives.</i>	263-9026	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
III. Radioactive Drug Research Committee <i>Reviews research involving radiopharmaceuticals that do not deliver an intended clinical benefit or that are not FDA approved.</i>	263-4856	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
William S. Middleton Memorial Veterans Hospital (VA) Research and Development Committee <i>Reviews all research protocols involving: 1) UW health sciences researchers with paid appointments at the VA; 2)</i>	256-1901, ext 7863 or 280-7007	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	

enrollment of subjects (including use of residual tissue and access to medical records) associated with the VA; or 3) use of VA facilities, e.g. space.

IV. Research Safety Committee <i>Reviews protocols possessing health hazards, such as gene transfer studies, and protocols intentionally exposing subjects to infectious agents.</i>	263-8902	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
V. Meriter Hospital Institutional Review Board	VI. 267-6411	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

II. Certification of Responsibility for the Application for the Initial Review of Research Involving Human Subjects, Completion of Human Subjects Protection Training Program by Key Personnel, and List of Personnel Who Will Use or Disclose Protected Health Information

Please list alphabetically the names, credentials, office addresses, and contact information for ALL University of Wisconsin-Madison investigators and other key personnel who are responsible for the design and conduct of this research. In addition, describe the role of each individual in the conduct of the study, and indicate whether the personnel will use or disclose PHI for this protocol as part of their research duties.

Name & Credentials /Job Title & Role /Contact Information	Will you request that this person have access to PHI from a primary source (e.g., WISCR, paper charts)?	Will this person use or disclose PHI?
Thomas Best Ph.D., M.D. – Doctor “On-Call” (608) 265-8415 tm.best@hosp.wisc.edu	NO	NO
Kreg Gruben Ph. D. – Primary Investigator (608) 262-2711 gruben@education.wisc.edu	NO	NO
Amit Mehta – Student Investigator (608) 347-0309 amitmehta@wisc.edu	NO	NO
Jon Millin – Student Investigator (920) 251-9366 jsmillin@wisc.edu	NO	NO
Ryan Pope – Student Investigator (920) 723-6532 poper@cae.wisc.edu	NO	NO
Jeff Swift – Student Investigator (920) 217-9131 jaswift@wisc.edu	NO	NO
Justin Williams Ph.D. – Project Advisor	NO	NO

(608) 265-3952 jwilliams@enr.wisc.edu		
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As Principal Investigator of this protocol, I take full responsibility for this Application for the Initial Review of Research Involving Human Subjects and certify that the key personnel listed above and I have completed the training module “Human Subjects Protection at the University of Wisconsin–Madison” available at <http://www.rsp.wisc.edu/humansubs/training/UWHSTraining.html>. I realize that: 1) this certification is to satisfy UW-Madison and NIH policy requirements; and 2) I am accountable for the accuracy of this certification.

Principal Investigator’s Signature

Date

Abstract

IN LAY TERMS using 300 words or less, please describe: 1) your research question; 2) your experimental design; 3) the major risks to subjects; 4) the potential benefits to subjects; and 5) your specific consent procedure(s). Please do NOT refer to sections of your protocol or to "see attached" in this abstract.

We aim to perform a pilot study to determine if patients with a variety of abilities are able to access an exercise machine and utilize all necessary components with minimal difficulty.

Our research focuses on the development of an accessible cycle ergometer (synonymous to a stationary exercise bike) for persons with a variety of disabilities such as: heart failure, diabetes, low vision, overweight, stroke, Parkinson’s disease, deaf, and blind. Subject participation in this study is completely voluntary. If they are willing to participate in the research, subjects will read and sign a consent form and complete a general health survey prior to initiating study. The post-experimental survey will be completed at the end of the participant’s study. The participants in the study will be between the ages of 18-70 and have at least one of the aforementioned disabilities. Participants with heart failure will not be required to exercise, only to sit in the device and assess their ability to enter and exit the machine. The cycle ergometer consists of foot pedals to allow for circular motion and thus, lower body workout. Furthermore, arm handles with forward and back motion to allow for the upper body workout. In addition to the implemented arm motion, heart rate monitor sensors are embedded in the handles to allow for heart rate output from the user’s palms. A maximum group of 10 subjects will be asked to participate including four control subjects for a total of 14 subjects testing the accessibility of the cycle ergometer. Subjects will be evaluated on ability to enter the device, situate themselves on the device, perform a short (approximately 5 minutes maximum) mild workout, and finally exit the device with little to no assistance. Participants have the option to terminate their experiment anytime should they be fatigued in any way, in shortness of breath, or for any other reason. Before each new experiment, the device (including the heart rate monitor sensors) will be sterilized with an antibacterial cleaner.

IV. Questionnaire

Please answer all of the following questions. If you answer "Yes" to any questions, please include details in Section V, *Study Description*. "Yes" answers also indicate that additional requirements may apply to your protocol.

VULNERABLE GROUPS:

VII. 1. Will this study involve minors (people less than 18 years old)?	VIII. X. <input type="checkbox"/> Yes	IX. XI. <input checked="" type="checkbox"/> No
XII. XV. 2. Will this study involve subjects who have a status relationship (e.g., students or employees) with the principal investigator(s)?	XIII. XVI. XVIII. <input type="checkbox"/> Yes	XIV. XVII. XIX. <input checked="" type="checkbox"/> No
XX. XXIII. 3. Will this study involve prisoners? <i>If Yes, are control group subjects randomly selected?</i> <i>If No, please provide justification in the study description.</i>	XXI. XXIV. XXVI. <input type="checkbox"/> Yes XXVIII. <input type="checkbox"/> Yes	XXII. XXV. XXVII. <input checked="" type="checkbox"/> No XXIX. <input type="checkbox"/> No
XXX. XXXIII. 4. Will this study recruit psychiatric inpatients or people who are institutionalized (e.g., in a mental health facility, nursing home, or halfway house)?	XXXI. XXXIV. XXXVI. <input type="checkbox"/> Yes	XXXII. XXXV. XXXVII. <input checked="" type="checkbox"/> No
XXXVIII. XL. 5. Will this study include women with childbearing potential?	XXXIX. XLII. XLIV. <input checked="" type="checkbox"/> Yes	XL. XLIII. XLV. <input type="checkbox"/> No
XLVI. XLVIII. 6. Will this study exclude fertile women?	LI. LV. LXII. <input type="checkbox"/> Yes	XLVII. L. LXIII. <input checked="" type="checkbox"/> No
LIII. LVII. 7. Will this study include subjects from the Middleton VA Hospital?	LVI. LXX. LXVIII. <input type="checkbox"/> Yes	LVII. LXXI. LXIX. <input checked="" type="checkbox"/> No
LXXI. LXXV. 8. Will this study include adults who have impaired decision-making capacity (e.g., coma, dementia, confusion, or mental disorders)?	LXXII. LXXVI. LXXVIII. <input type="checkbox"/> Yes	LXXIII. LXXVII. LXXIX. <input checked="" type="checkbox"/> No
LXXX. LXXXIII. 9. Will this study include gametes, embryos, fetuses, or involve tissues from embryos or fetuses?	LXXXI. LXXXIV. LXXXVI. <input type="checkbox"/> Yes	LXXXII. LXXXV. LXXXVII. <input checked="" type="checkbox"/> No
LXXXVIII. LXXXIX. 10. Will this study target or exclude a particular ethnic or racial group?	LXXXIX. LXXXIII. LXXXIV. <input type="checkbox"/> Yes Yes	LXXX. LXXXII. LXXXV. <input checked="" type="checkbox"/> No
SPECIAL PROCEDURES:		
XCVI. 11. Will this study involve an investigational new drug (IND)? <i>If Yes, please provide the IND # _____</i> <i>If you hold the IND, please provide 3 copies of the application submitted to the FDA</i>	XCVII. XCIX. <input type="checkbox"/> Yes	XCVIII. C. <input checked="" type="checkbox"/> No
CI. CIV. 12. Will this study involve an investigational device? <i>If Yes, please provide the IDE# _____ and 3 copies of the IDE specifications</i>	CV. CVII. <input type="checkbox"/> Yes	CVIII. CVIII. <input checked="" type="checkbox"/> No
CIX. CXX. 13. Will this study involve the administration to subjects of radiopharmaceuticals that are not FDA approved? <i>If Yes, please contact the secretary for the Radioactive Drug Research Committee (RDRC) at 263-4856.</i>	CX. CXIII. CXV. <input type="checkbox"/> Yes	CXII. CXIV. CXVI. <input checked="" type="checkbox"/> No

Note: If you answer Yes to question 14, 15, or 16 you should consult HS-IRB Guidelines for Genetic Research and the Use of Storable Tissues for potential consent form language. You should also complete the tissue collection information sheet in those Guidelines and attach it to this form.

<small>CXXIII CXXVI</small> 14. Will this study store blood or tissue samples beyond publication of the study results?	<small>CXXIV CXXVII</small> CXXIX. <input type="checkbox"/> Yes	<small>CXXV CXXVIII</small> CXXX. <input checked="" type="checkbox"/> No
<small>CXXXI CXXXIV</small> 15. Will this study use an existing depository or collection of blood or tissue samples?	<small>CXXXII CXXXV</small> CXXXVII. <input type="checkbox"/> Yes	<small>CXXXIII CXXXVI</small> CXXXVIII. <input checked="" type="checkbox"/> No
<small>CXXXIX CXLII</small> 16. Will this study do testing for genetic markers on blood or tissue samples?	<small>CXL CXLIII</small> CXLV. <input type="checkbox"/> Yes	<small>CXLI CXLIV</small> CXLVI. <input checked="" type="checkbox"/> No
<small>CXLVII CL</small> 17. Will this study involve the administration to subjects of recombinant DNA materials? <i>If Yes, consult the staff of the Biological Safety Office at 263-9026.</i>	<small>CXLVIII CL</small> CLIII. <input type="checkbox"/> Yes	<small>CXLIX CLII</small> CLIV. <input checked="" type="checkbox"/> No
SPECIAL POLICIES:		
<small>CLV CLVIII</small> 18. Will this study use a placebo?	<small>CLXII</small> CLXIV. <input type="checkbox"/> Yes	<small>CLXIII</small> CLXV. <input checked="" type="checkbox"/> No
<small>CLXVI CLXIX</small> 19. Will this study potentially reveal that subjects engaged in illegal behaviors or stigmatizing behavior (e.g., illicit drug use, child abuse, alcoholism, or gambling)?	<small>CLXX</small> CLXXII. <input type="checkbox"/> Yes	<small>CLXXI CLXXIV</small> CLXXIII. <input checked="" type="checkbox"/> No
<small>CLXXIV CLXXVII</small> 20. Is this study minimal risk?	<small>CLXXV CLXXVIII</small> CLXXX. <input checked="" type="checkbox"/> Yes	<small>CLXXVI CLXXIX</small> CLXXXI. <input type="checkbox"/> No
<small>CLXXXII CLXXXV</small> 21. Are you requesting a waiver of written consent?	<small>CLXXXIII CLXXXVI</small> CLXXXVIII. <input type="checkbox"/> Yes	<small>CLXXXIV CLXXXVII</small> CLXXXIX. <input checked="" type="checkbox"/> No
<small>CXC CXCI</small> 22. Will this study use advertising, recruitment letters, or recruitment posters to invite subject participation? <i>If Yes, please attach copies of these materials to this form.</i>	<small>CXCII CXCV</small> CXCVI. <input checked="" type="checkbox"/> Yes	<small>CXCIII CXCVI</small> CXCVII. <input type="checkbox"/> No
<small>CXCVIII CCL</small> 23. Will this study use questionnaires, surveys, or other written assessment instruments? <i>If Yes, please attach of copy of these materials to this form.</i>	<small>CXCIX CCL</small> CCIV. <input checked="" type="checkbox"/> Yes	<small>CC CCIII</small> CCV. <input type="checkbox"/> No
<small>CCVI CCIX</small> 24. Will this study involve non-UW researchers?	<small>CCVII CCX</small> CCXII. <input type="checkbox"/> Yes	<small>CCVIII CCXI</small> CCXIII. <input checked="" type="checkbox"/> No
<small>CCXIV CCXVII</small> 25. Will you conduct this study outside of the United States?	<small>CCXV CCXVIII</small> CCXX. <input type="checkbox"/> Yes	<small>CCXVI CCXIX</small> CCXXI. <input checked="" type="checkbox"/> No
<small>CCXXIII CCXXV</small> 26. Where will you conduct this study? <input checked="" type="checkbox"/> UWHC <input type="checkbox"/> Middleton VA Hospital <input type="checkbox"/> Meriter Hospital <input type="checkbox"/> Other site(s) – Please list:	<small>CCXXIV CCXXVI</small>	<small>CCXXV CCXXVIII</small>

V. Study Description

IN NO MORE THAN 2000 WORDS (A MAXIMUM OF 4 PAGES) please describe your study in the format outlined below. A study description longer than four pages or a faxed copy of your study description is **NOT** acceptable and will **NOT** receive assignment for review. Please do **NOT** refer to sections of your protocol or to “see attached” in your study description.

- A. Explain the benefit to society that would result if you perform your study. Concisely identify the study's purpose in the context of currently available and relevant knowledge.

There are a variety of disabilities people can have that would impair their ability to lead a normal, functional life. Some of these disabilities include partial or complete loss of vision, loss of motor control, and other sensory deficits (e.g. touch). These disabilities can not only directly affect a specific function of a person's body, but also cause other harm to the person due to a loss of functionality. Many times, someone who has lost sensory information or some motor control will be unable to exercise and maintain a healthy lifestyle. An ergometer device that offers users with a variety of disabilities the ability to exercise will allow these individuals to lead a healthier lifestyle and ultimately increase their quality of life.

- B. Describe the design of your study. In the case of clinical research, use care to distinguish experimental interventions from standard medical treatment. Indicate how long the project will take to complete and provide start and end dates.

Subjects will be asked to use an ergometer device designed to allow users with disabilities to exercise. It is hoped that the device will allow people with disabilities to lead a more active and healthier lifestyle. Upon approval from HSC, the study will be conducted between 4/5/2005 – 4/10/2005 in G5/170-174. A representative from the group will be present throughout the duration of the study.

- C. Describe your subject population and recruitment methods. Who will be the subjects of your study? Where will you find these subjects? How many subjects will the entire study enroll? How many subjects will you enroll at your site? How many subjects are controls? If the research involves more than two study arms, please identify each one and the expected number of subjects. List the primary criteria for subject selection and exclusion. What method(s) will you use to recruit subjects? Will these methods involve material inducements? Indicate whether any project personnel will receive incentives for recruiting human subjects or for any other purpose directly related to the study.

Subjects for this study will come from the Madison community between the ages of 18-70. Both individuals with normal motor control and sensory systems and those with loss of motor control and sensory system dysfunction will be used as subjects. Our study will enroll four control subjects and up to ten experimental subjects. Subjects with loss of motor control and sensory system dysfunction will be recruited through hospital advertisement and by invitation. Advertisements will be placed in the following areas: School of Nursing, UW Faculty and staff newsletter and email, campus billboards, and newspaper ads. Interested individuals can contact us via email or telephone. If contacted via telephone, a phone screening form will be filled out in which we will provide the interested participant with a subject number and designate a time that works for them to conduct the study. In addition, we will make sure that, if a patient of the UW-Hospital, the patient is cleared with his/her primary care physician. We will then attempt to set up an appointment with that patient to conduct the experiment at the UW-Hospital (Room G5/170-174). In addition to the participants, there will be four control subjects that will perform the experiment identical to the participants. All subjects will be asked to participate in a single experimental session. Participation in this study is entirely voluntary. No monetary compensation will be provided.

- D. If the study is more than minimal risk, describe the data and safety monitoring plan. If a formal Data Safety Monitoring Board or Data Monitoring Committee exists, provide a general description of the committee or board's membership e.g. number of members, expertise, and whether the members are independent of the sponsors/researchers) and the expected frequency of their meetings.

The study is minimal risk.

- E. Does your study have a statistical justification for its sample size? For the analysis of its results? If you answer "yes" to these questions, briefly describe each justification.

No, the results will be insignificant due to the small sample size.

- F. Identify the potential risks to subjects of participation in your study. Describe the expected frequency, severity, and reversibility of the major risks you identify. Include possible late effects of participation (e.g., secondary cancers).

The subjects we will be testing will have either a loss of motor control or sensory system deficiencies. If the subjects feel any discomfort or shortness of breath, they can terminate their exercise immediately. Heart rate will be monitored while the test is conducted, and the subject will stop the exercise immediately if their heart rate becomes 60 percent of their maximum heart rate determined by the age-adjusted formula:

Male: $210 - (1/2 \text{ your age}) - (.05 \times \text{your body weight}) + 4$

Female: $226 - (1/2 \text{ your age}) - (.05 \times \text{your body weight})$.

Because the same ergometer will be used by multiple subjects, there is the possibility for disease transmission. This risk is reduced to an extremely small amount by material sterilization. Any material that may come in contact with a subject will be first sterilized. Prior to experiments, subjects will complete a questionnaire (attached) to assess general health and to identify certain conditions that may contraindicate participation in this study (e.g. severe heart problems, paraplegic). This information will be held confidential.

Because we are striving to develop an ergometer that is accessible to people with motor control and sensory disabilities, we must test the device under conditions that allow us to determine improvements that are necessary to alleviate problems encountered with these disabilities. The device, and therefore the study, is designed to minimize these risks to the subject. There will be four supervising experimenters present during testing. At the time the testing will commence, one of the experimenters will be certified in Adult and Infant CPR from the American Red Cross. In the event of a medical emergency, three of the experimenters will attend to the subject while the other will contact Emergency Services at 9-9-1-1.

- G. Identify the expected benefits to subjects of participation in your study. Also identify any potential scientific benefits produced by your study.

We do not expect that the system will provide any practical benefit to our clinical subjects. However, it is hoped that this research will aid the subsequent development of an accessible ergometer for not only persons with motor control and sensory problems, but also for persons with a wide range of disabilities.

- H. Describe the procedure for obtaining the consent of each subject or the subject's parent or representative. Confirm that you have attached a copy of each consent form. The form should include all the elements of consent listed in the HS-IRB Guidelines.

Prior to data collection, all individuals interested in participating will be required to read and sign a copy of the attached consent form. Those individuals that are blind or have low vision will have the

consent form read to them by a family member, friend, or another disinterested party. This will be arranged during the phone screening, ensuring that the blind/low vision participant will either have someone come with them to read the consent form to them or that we will make the necessary arrangements for a disinterested party to be present.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Accessible Ergometer Information

Invitation/Summary

You are invited to participate in a research project designed to evaluate how well people can use a special, new cyclic ergometer (exercise bike) and perform proper entry and exit to the device with little to no assistance and still obtain an aerobic workout. You have been invited to participate in this research because you have a condition(s) including: Heart Failure, Diabetes, Low Vision, Overweight, Stroke, Parkinson's disease, Deaf, and/or Blind. During the research study, you will be asked to enter the device and sit yourself comfortably on the exercise seat. You will then perform a short workout in which you will perform lower body workout by pedaling with your feet and/or perform upper body workout by pushing and pulling the handles. During your exercise, the heart rate monitor sensors embedded in the handles will monitor your heart rate. Lastly, we will observe you as you exit the device. We are interested in learning how patients with a variety of abilities would be able to access this device and if they can do it with minimal effort and still obtain a good workout. We intend to test the device on a maximum of 10 individuals with the conditions listed above, along with 4 control individuals that do not have any of the listed conditions.

What does study participation involve?

If you decide to start the trial, you will be asked to enter the exercise device and sit on the seat. You can make any adjustments to the seat height, its distance from the foot pedals, and arm handles until you are fully comfortable. We will observe your ease of entering the device as well as examine any necessary adjustments you made to the device. We will then ask you to perform a short workout (approximately five minutes) in which you can pedal with your feet and move the arm handles at the same time or separately. During your exercise, we will closely monitor your ability to use the machine and watch your heart rate from the heart rate monitor sensors embedded in the handles. At the end of your exercise, we will then ask you to exit the device with little to no assistance and, again, observe your ability to do so. At the start of the experiment, we will ask you to complete a general health inquiry. At the conclusion of the experiment, we will ask you to complete a post experimental survey. The information you provide will be kept confidential. Each test session should last a maximum of half hour with about five minutes of actual exercise time.

Is there any discomfort or risk?

The same exercise bike will be used by several subjects. To prevent germs from being spread and to clean the heart rate monitor sensors, prior to each trial the device will be sanitized with antibacterial cleaners. This is used to clean the heart rate monitor sensors. There is also the risk of temporary muscle fatigue/strain with the possibility of

accompanied muscle soreness that is expected with new exercise routines. This soreness should diminish within 2 to 3 days without treatment.

Will compensation be paid in the event of an injury?

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize that you have not released this institution from liability for negligence. Please contact the Principal Investigator, Kreg Gruben Ph.D., at (608) 262-2711 if you are injured or for further information.

Where will the study take place?

The study will take place at the UW Hospital in G5/170-174. Sessions will last half hour at the maximum with about five minutes of exercise.

Will my study results be confidential?

Your name or other identifying information will not be revealed in publications or reports that may result from this study, nor will your name be used in other research communications such as lectures or scientific meetings. Data obtained from the Health Questionnaire will be kept strictly confidential.

Will I be paid for my participation?

No, you will not be paid for being in this study.

Is there any benefit to participation?

You will not personally benefit from participation, but society may benefit from the creation of an assessable exercise bike that is usable by patients of various abilities and being universally applicable to all users.

What if I change my mind?

Participation in this study is voluntary. If you change your mind at any time you are free to end the session and to withdraw from the study. If you decide not to participate or to withdraw, it will not affect your status as a student or employee at the University of Wisconsin or your treatment at the University of Wisconsin Hospitals and Clinics.

You may take as much time as you need to make up your mind whether to participate in this study. Before you sign this form, please ask any questions you wish on the aspects of the study that are not clear to you. We will attempt to fully answer any questions you may have prior to, during, or following this study.

What if I have questions?

For questions regarding the research study, contact Dr. Kreg Gruben at (608)262-2711 or gruben@education.wisc.edu. For questions regarding your rights as a research subject, contact the UW Patient Relations Representative at (608)263-8009.

AUTHORIZATION:

I, _____, have read, or have had read to me, the above and I have decided to participate in the research project described above. My signature also indicates that I have received a copy of this consent form.

Signature

Date

I was present while this consent form was read to the subject and can confirm that what was read to the subject is the same information that is contained in the written document the subject has signed.

Signature of Witness

Date

Signature of Principal Investigator
or of person obtaining consent

Telephone

University of Wisconsin-Madison
Department of Biomedical Engineering

ACCESSIBLE ERGOMETER RESEARCH

-Pre-Experimental General Health Inquiry-

Thank you for your willingness to participate in this experiment. We request some background information about our research participants. All information provided here will be held strictly confidential and none of it will be used to identify you should reports, presentations, or publications result from the data. However, granting agencies and research journals often request summary statistics regarding age and other physical characteristics, ethnic background, and gender of research participants. Additionally, FDA regulations permit the FDA or University of Wisconsin Human Subjects Committee to examine certain records upon request to ensure compliance with applicable statutes. Thus, for reasons of privacy, **you may choose not to provide certain information.**

Study Number: _____

Date of birth: _____

Height: _____ Weight: _____ Gender: _____ If Female, are you pregnant? _____

Ethnic Background: Please choose from the list below: _____

- | | | |
|---------------------------------------|-------------------------------|-------------------------|
| 1 = American Indian or Alaskan Native | 2 = Asian or Pacific Islander | 3 = Black, not Hispanic |
| 4 = Hispanic | 5 = White, not Hispanic | 6 = Other or Unknown |

General physical health:

Do you currently have any of the following ailments? (Check all that apply)*

- | | | |
|------------------|---------------------------|---------------------------------------|
| _____ Blind | _____ Deaf | _____ Heart Failure |
| _____ Stroke | _____ Parkinson's disease | _____ Diabetes
(Type I or Type II) |
| _____ Low Vision | | |

Other Comments: _____

*This question is not required for you to answer, but if left blank, experiment results will be insignificant.

- Post Experimental Survey -

How do you rate the ability to enter the machine [on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate the ability to adjust the seat to your liking on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate the ability to adjust the resistance level of exercise to your liking on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate the ability to use the foot pedals to perform lower body workout on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate the ability to use the arm handles to perform upper body workout on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate the ability to read the control screen on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate your total exercise experience [on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How do you rate the ability to exit the machine on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

Did you find the seat assist helpful [yes or no]? _____

How do you rate your experience using our prototype today on a scale of 1-10, with 10 being the easiest and 1 being the hardest]? _____

How would you improve this device? _____

Other comments or questions? _____

Phone Screening Form

This form outlines the procedure to screen potential participants for the accessible ergometer study. When receiving a call from an interested participant, be sure to assign him/her a subject number and complete all the information below. **Be sure to note the participant's specific disability in the "Special considerations" section of this form.** This form will be destroyed at the conclusion of the study.

Last Name (optional) _____

First Name _____

Contact information (any one is acceptable)

Phone _____

E-Mail _____

If patient of UW-Hospital, clearance obtained from primary care physician? [Y/N] _____

Date & time available for study _____

Special considerations/other _____

Name of phone screener

University of Wisconsin – Madison
 Health Sciences Human Subjects Committee
 2500 Overlook Terrace #B3088 Madison, WI 53705
PROTOCOL CLOSURE REPORT

Instructions: Please note that a protocol previously approved by the Human Subjects Committee (HSC) should be closed if the protocol has been completed (including subject participation, subject follow-up, long-term observation, and data analysis) or if the study is terminated. Please complete the following information and submit one original to the HSC office.

Principal Investigator Name: Kreg Gruben	
Protocol Title: Accessible Ergometer	
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1. Reason for Protocol Closure/Termination:

- Protocol and Data Analysis Complete
- Protocol Terminated (Specify reason _____)
- Lack of Funding or Funding Not Renewed
- Other

(Explain: _____)

2. Enrollment:

Total number of subjects enrolled or samples obtained 4 control subjects, 4 experimental subjects
 Total number of subjects who completed participation/number of samples analyzed 4 control subjects, 4 experimental subjects

3. Adverse Events (AE's):

Number of serious AND unexpected related to study treatment or intervention 0

Previously reported to the HSC? Yes No (If no, please attach an Adverse Event Report for HSC review)

Number of UW or VA subject deaths _____

Previously reported to the HSC? Yes No (If no, please attach an Adverse Event Report for HSC review)

 Signature of Principal Investigator

 Date