

University of Wisconsin-Madison

## Application for Initial Review of Research Projects Involving Human Subjects

Health Sciences IRB ▪ Health Sciences Minimal Risk IRB

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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
  
3. Co-Investigator/Student/Resident/Fellow (if applicable)  
Name:  
Job Title:  
Department/Unit Name:  
Office Address:  
Phone & Pager:  
Fax:  
Email:
  
4. Point of Contact (person to whom correspondence should be sent, if other than PI)  
Name:  
Job Title:  
Department/Unit Name:  
Office Address:  
Phone & Pager:  
Fax:  
Email:

#### 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?  
If yes, list the names of those companies/business entities.  Yes  No
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.

<b>Committee</b>	<b>Phone</b>	<b>Review Required?</b>	<b>Review Date</b>
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	
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) 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.</i>	256-1901, ext 7863 or 280-7007	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
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	
Meriter Hospital Institutional Review Board	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?
<b>Thomas Best Ph.D., M.D. – Doctor “On-Call”</b> (608) 265-8415 tm.best@hosp.wisc.edu	NO	NO
<b>Kreg Gruben Ph. D. – Primary Investigator</b> (608) 262-2711 gruben@education.wisc.edu	NO	NO
<b>Amit Mehta – Student Investigator</b> (608) 347-0309 amitmehta@wisc.edu	NO	NO
<b>Jon Millin – Student Investigator</b> (920) 251-9366 jsmillin@wisc.edu	NO	NO
<b>Ryan Pope – Student Investigator</b> (920) 723-6532 poper@cae.wisc.edu	NO	NO
<b>Jeff Swift – Student Investigator</b> (920) 217-9131 jaswift@wisc.edu	NO	NO
<b>Justin Williams Ph.D. – Project Advisor</b> (608) 265-3952 jwilliams@enr.wisc.edu	NO	NO

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

### III. 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:**

- |   |  |   |
|---|--|---|
| 1. Will this study involve minors (people less than 18 years old)?  | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 2. Will this study involve subjects who have a status relationship (e.g., students or employees) with the principal investigator(s)?  | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 3. Will this study involve prisoners?<br><i>If Yes, are control group subjects randomly selected?</i><br><i>If No, please provide justification in the study description.</i> | <input type="checkbox"/> Yes<br><input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No<br><input type="checkbox"/> No |
| 4. Will this study recruit psychiatric inpatients or people who are institutionalized (e.g., in a mental health facility, nursing home, or halfway house)?                    | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 5. Will this study include women with childbearing potential?   | <input checked="" type="checkbox"/> Yes                      | <input type="checkbox"/> No   |
| 6. Will this study exclude fertile women?   | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 7. Will this study include subjects from the Middleton VA Hospital?   | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 8. Will this study include adults who have impaired decision-making capacity (e.g., coma, dementia, confusion, or mental disorders)?  | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 9. Will this study include gametes, embryos, fetuses, or involve tissues from embryos or fetuses?   | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |
| 10. Will this study target or exclude a particular ethnic or racial group?  | <input type="checkbox"/> Yes                                 | <input checked="" type="checkbox"/> No                                |

**SPECIAL PROCEDURES:**

- |   |                              |  |
|---|------------------------------|--|
| 11. Will this study involve an investigational new drug (IND)?<br><i>If Yes, please provide the IND # _____</i><br><i>If you hold the IND, please provide 3 copies of the application submitted to the FDA</i>                      | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| 12. Will this study involve an investigational device?<br><i>If Yes, please provide the IDE# _____ and 3 copies of the IDE specifications</i>   | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| 13. Will this study involve the administration to subjects of radiopharmaceuticals that are <b>not</b> FDA approved?<br><i>If Yes, please contact the secretary for the Radioactive Drug Research Committee (RDRC) at 263-4856.</i> | <input type="checkbox"/> Yes | <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.**

- |   |                              |  |
|---|------------------------------|--|
| 14. Will this study store blood or tissue samples beyond publication of the study results?  | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| 15. Will this study use an existing depository or collection of blood or tissue samples?  | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| 16. Will this study do testing for genetic markers on blood or tissue samples?  | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |
| 17. Will this study involve the administration to subjects of recombinant DNA materials?<br><i>If Yes, consult the staff of the Biological Safety Office at 263-9026.</i> | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> No |

**SPECIAL POLICIES:**

18. Will this study use a placebo?  Yes  No
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)?  Yes  No
20. Is this study minimal risk?  Yes  No
21. Are you requesting a waiver of written consent?  Yes  No
22. Will this study use advertising, recruitment letters, or recruitment posters to invite subject participation?  
*If Yes, please attach copies of these materials to this form.*  Yes  No
23. Will this study use questionnaires, surveys, or other written assessment instruments?  
*If Yes, please attach of copy of these materials to this form.*  Yes  No
24. Will this study involve non-UW researchers?  Yes  No
25. Will you conduct this study outside of the United States?  Yes  No
26. Where will you conduct this study?  
 UWHC  
 Middleton VA Hospital  
 Meriter Hospital  
 Other site(s) – Please list:
-

## 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.