

UNIVERSITY OF ILLINOIS
AT URBANA - CHAMPAIGN

Office of the Vice Chancellor for Research
Institutional Review Board
528 East Green Street
Suite 203
Champaign, IL 61820



January 13, 2009

Robert Motl
Kinesiology & Community Health
350 Freer Hall
M/C 052

RE: *Physical activity stress and exacerbations in MS*
IRB Protocol Number: 09222

Dear Robert:

Thank you very much for forwarding the modifications to the University of Illinois at Urbana-Champaign Institutional Review Board (IRB) office for your project entitled *Physical activity stress and exacerbations in MS*. I will officially note for the record that these major modifications to the original project, as noted in your correspondence received December 19, 2008: adding the use of a Yamax SW-200 pedometer as an objective measure of physical activity for both Phase I and Phase II; change in remuneration allowing the participants to keep the pedometer after data collection; and adding self-report questionnaire "Relapses or Progression of symptoms in MS to the measures" (participants will complete the questionnaire during Phase I and every month during Phase II), have been approved. The expiration date for this IRB protocol, UIUC number 09222, is 11/04/2009. The risk designation applied to your project is *no more than minimal risk*.

As your modifications involved changes to the consent form, I am enclosing the revised form with date-stamp approval. Please note that copies of date-stamped consent forms must be used in obtaining informed consent. If modification of the consent form is needed, please submit the revised consent form for IRB review and approval. Upon approval, a date-stamped copy will be returned to you for your use.

Please note that additional modifications to your project need to be submitted to the IRB for review and approval before the modifications are initiated. To submit modifications to your protocol, please complete the IRB Research Amendment Form (see <http://irb.illinois.edu/?q=forms-and-instructions/research-amendments.html>). Unless modifications are made to this project, no further submittals are required to the IRB.

We appreciate your conscientious adherence to the requirements of human subject research. If you have any questions about the IRB process, or if you need assistance at any time, please feel free to contact me or the IRB Office, or visit our Web site at <http://www.irb.illinois.edu>.

Sincerely,

Sue Keehn, Director, Institutional Review Board

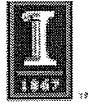
Enclosure

c: Yoojin Suh
Madeline Weikert

telephone 217-333-2670 • fax 217-333-0405 • email IRB@illinois.edu

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Department of Kinesiology and Community Health
College of Applied Health Sciences
Louise Freer Hall
906 South Goodwin Avenue
Urbana, IL 61801-3895



INFORMED CONSENT

Physical Activity, Stress, and Exacerbations in Multiple Sclerosis

You are invited to participate in our research study of physical activity, stress, and exacerbations among people with Multiple Sclerosis. The study is being conducted by Dr. Robert Motl and Ms. Madeline Weikert and Ms. Yoojin Suh all of the Department of Kinesiology and Community Health at the University of Illinois. The following statements inform you of what will be required of you. Please read it carefully. If you have any questions please ask.

The study involves two phases. Before you can participate in either phase, you will be asked to sign this informed consent. After signing the signed informed consent, you will begin the 1st phase of the project. This will initially involve completing a booklet of 9 questionnaires. The questionnaires will take approximately 30 minutes to complete. After you complete the questionnaires, you will wear a pedometer daily during the waking hours of a 7-day period. You will return the completed questionnaires, but keep the pedometer, in the self-addressed, stamped envelope that came in the mail. After we receive the materials, Madeline Weikert will contact you over the phone and conduct a recall of your exacerbations during the previous year.

After finishing the 1st phase, we will initiate the 2nd phase of the study. This will involve completing a booklet of 6 questionnaires and then wearing the pedometer for a 7-day period every month across a 1-year period of time. If you report experiencing an exacerbation in any of the months, Madeline Weikert will contact you over the phone and conduct a recall of your exacerbation.

Your participation in this research is voluntary and you must be a woman between 18 and 64 years of age to participate. You may refuse to participate, discontinue participation, or skip any questions you do not wish to answer at any time without penalty or loss of the benefits to which you are otherwise entitled.

There are minimal risks associated with completing the measures for this project. The only foreseeable risks may be psychological in that non-active participants may experience some guilt or discomfort reporting non-activity and some individuals may experience discomfort in reporting stressful events. The primary benefit of this research involves further understanding of the roles of physical activity and stress as triggers of exacerbations among people with MS. This is important for understanding possible targets for increasing physical activity levels of those with MS, and thereby promoting the many health benefits of an active lifestyle. You will be paid a total of \$15.00 and given a pedometer for completing Phase 1. You will be entered into a drawing for one of ten \$50.00 prizes for completing Phase 2.

Only Dr. Motl and members of the research team will have access to research results associated with your identity. The results of the study will be presented at scientific conferences

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and published in scientific journals. In the event of presentation and publication of this research, no personally identifying information will be disclosed.

If you have any problem or have any questions at any time during your participation in this study, please feel free to make a collect call to Dr. Robert Motl, Department of Kinesiology and Community Health, University of Illinois, telephone (217) 265-0886, e-mail robmotl@uiuc.edu.

I have read and understand the informed consent provided by Dr. Motl, Ms. Weikert, and Ms. Suh. I voluntarily agree to the procedures outlined above and willingly consent to be a participant in this study. You will be given a copy of the informed consent form.

Name (please print)

Signature

Date

Researcher Name

Signature

Date

If you have questions about your rights as a research subject, please contact the Institutional Review Board at IRB Office, 528 East Green Street, Champaign, IL 61820, Phone: 217.333.2670, Fax: 217.333.0405, E-mail: irb@uiuc.edu. Collect calls are invited by the IRB Office if you live outside the local calling area.

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APPROVED CONSENT
VALID UNTIL

NOV -4 2009