NORWALK COMMUNITY COLLEGE
Institutional Review Board Application

CONTACT INFORMATION

Principal Investigator: _____
Institutional Affiliation: _____
E-mail address: _____
Phone number: _____
Mailing address: _____
_____

Title of the Study: **The association of muscular weakness and treadmill-based walking economy in older men and women.**

Please list the names of all additional researchers who will be involved in the study below. Please give their names and institutional affiliations:

Name	**Institution**	**IRB Certification Information** **Required for any researchers who will be on-site at NCC. Include source and date.**

Please note: Principal Investigators are required to provide evidence that IRB training has been completed with this application. In addition, any researchers who will be on-site at NCC must provide evidence of training prior to data collection.

BACKGROUND INFORMATION

1. Who will your potential subjects be? Please check the subject population/s that will be involved in the research project:

[ ] Adults (18 and over, competent to consent)

[ ] Minors (under 18 years old)

[ ] Prisoners

[ ] Pregnant women

[ ] Developmentally disabled Describe: _____

[ ] Non-English speakers

2. Please describe the anticipated age range, gender, race/ethnicity (if applicable) and/or any other important characteristics of your subjects:

3. Please describe in 300 words or less the purpose of your research. Provide relevant background information and scientific justification for your study. You may provide citations as necessary.

4. Please state your research question (in one or two sentences).

5. Please describe the *specific data* you plan to collect (300 words or less).

6. Please identify the names of an institutions and/or funders that are sponsoring your research. If your research is sponsored by an institution other than Norwalk Community College, you must include evidence of IRB approval from that institution with your application. If your research is grant funded, please provide the name of the organization funding your research and your grant award number.

DESCRIPTION OF RECRUITMENT AND PROCEDURES

7. Please describe your recruitment methods. **How** and **where** will subjects be recruited (flyers, announcement/s, word-of-mouth, snowballing, etc.)? You will need to include your IRB Protocol number in all recruitment materials, including announcements, online and email text. Paper copies of submitted recruitment materials to be distributed will be stamped with your IRB Protocol number once your study has been approved. Federal guidelines state that research cannot exclude any classes of subjects without scientific justification. Will your study purposely exclude any classes of subjects (e.g. by gender, class, race or age)? If so, please justify.

8. Are you recruiting subjects from institutions other than Norwalk Community College? If so, please describe.

9. How many subjects are you planning to recruit?

10. Please describe what *activities* your subject will be engaging in (e.g. surveys, focus groups, interviews, diagnostic procedures, etc.).

11. How long will your subjects participate in this study (duration of activities and overall duration of study)? Please provide more detailed description, charts, etc. if needed for clarification, and indicate all that may apply:

12. Where will your research take place specifically (e.g., in classroom, outside of classroom, waiting room, office, other location)?

13. Will subjects be remunerated for their participation? If, so please describe. [**PLEASE NOTE:** If using a lottery system, please remember to state odds of winning in consent form].

14. Will deception be used? If so, please provide a rationale for its use. How will subjects be debriefed afterward? Submit debriefing script. Scripts should include a statement that gives your subjects the opportunity to withdraw their participation at that time. [**PLEASE NOTE:** studies involving deception are given **Full Board Review** unless the deception is minor and risks are minimal].

15. Will you have a control group? Please describe your procedures and explain the purpose of using a control group.

16. Will you be videotaping your subjects? If so, please describe in detail. [**PLEASE NOTE**: The IRB will only approve videotaping when there is adequate scientific and ethical justification].

CONFIDENTIALITY PROCEDURES

17. How will you ensure the subjects' confidentiality? Describe in detail your plans for ensuring confidentiality of data regarding subjects. [**PLEASE NOTE**: If you will be remunerating subjects after their participation, please make it clear if and how you will link their names/contact information confidentially to their compensation].

18. Will data be collected anonymously? Will you be able to link the data? If data will not be collected anonymously, how will subjects' identity/ information be protected? (e.g. codes, pseudonyms, masking of information, etc.)?

19. Where will coding and data materials be stored (e.g. 'in a locked file cabinet in the Principal Investigator's home or office')?

20. How will Norwalk Community College be identified in reports, papers and presentations resulting from this study? Do you plan to present disaggregated data from NCC, and if so, how will you ensure that research subjects cannot be directly or indirectly identified?

DESCRIPTION OF RESEARCH RISKS & BENEFITS

21. What are the potential risks, if any, (physical, psychological, social, legal, or other) to your subjects? What is the likelihood of these risks occurring, and/or their seriousness? How will you work to minimize them? [**PLEASE NOTE**: The IRB regards no research involving human subjects as risk-free. You may describe minimal risks for your study (such as discomfort, boredom, fatigue, etc.), or state that the research will involve minimal risk, similar to an activity (named) like that which participants will perform as part of your study.]

22. What are your plans for ensuring necessary intervention in the event of a distressed subject and/or your referral sources if there is a need for psychological and/or physical treatment/assistance?

23.

24. What are your qualifications/preparations that enable you to estimate and minimize risk to subjects?

INFORMED CONSENT PROCEDURES

25. What are your procedures for obtaining subject's informed consent to participate in the research? If you will be audio/videotaping, please state how you will ensure that subjects have consented to being recorded, and if some subjects do not consent to being recorded, explain how you will protect their confidentiality. (This must also be clearly stated in your consent form/s).

26. How will you describe your research to potential subjects?

27. What will you do to ensure subjects' understanding of the study and what it involves?

28. If you are recruiting students from a classroom during normal school hours, what will the **alternative** activities be for those who wish not to participate? (This should also appear in your consent form/s)

29. Are you currently a member of the faculty, staff, or administration of Norwalk Community College, or in any other way affiliated with the College? If so, how will you insure voluntary

participation and minimize the appearance of coercion, bias or undue influence in your study?

Submit all consent forms/scripts, using the template on the IRB website. **Drafts of consent forms will not be accepted.** Each consent form must be a separate document and titled for its respective subject population (e.g. teachers, parents, etc.). All consent documents must be in English, even though you may translate them. If your research project requires using documents that are translated into other languages, please submit both the translated English version AND the translated document with your application.

RESEARCH SITE/S

30. Where will research be conducted? If you are conducting research or any part of your study, or recruiting subjects from schools or other institutions, approval must be obtained from the appropriate administrator, IRB, or representative of that institution.

ATTACHMENTS:

You must attach Informed Consent, Participants' Rights and Assent for Minors, Recruiting materials, survey materials, etc. as appropriate.

Submit Form to:

Dr. Paul M. Gallo, Ed.D.
Director of Exercise Science and Wellness
Institutional Review Board Chair
Norwalk Community College
pgallo@norwalk.edu