

**AC 2007-1194: 75 UNDERGRADUATE STUDENTS OBTAIN MOTIVATING  
EXPERIENTIAL EDUCATION BY PARTICIPATING IN A HUMAN CLINICAL  
TRIAL WHILE PERFORMING BIOMEDICAL ENGINEERING RESEARCH**

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## **54 Undergraduate Students Obtain Clinical Experiential Education as Participants in Biomedical Engineering Research**

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*Objective:* To implement an effective experiential education research project designed to educate undergraduate students about the human clinical trial research process, while it enhances their understanding of healthy fitness habits.

*Background:* Experiential education has been demonstrated to be effective in medical and nursing schools. In biomedical engineering, research and clinical care are inextricably linked. Nonetheless, opportunities for undergraduate biomedical engineering students to participate in clinical research are limited, and in most cases, offer only individual training. This experience is particularly challenging to offer in engineering schools that do not have medical school affiliations. It was hypothesized that a motivating experiential education research project, in the context of a human clinical trial, could be conducted at an engineering school. The focus of the investigation involves the prevention of obesity, clearly an educational challenge. Students participating in an experiential educational research program regarding obesity prevention could effectively learn about clinical research while enhancing their personal fitness habits.

*Methods:* 74 undergraduate college students age 18-22 were recruited as volunteer subjects and studied for one year. Six students also participated as part time research assistants. The study was approved by the IRB. Informed consent was obtained, and a sports medicine physician screened the health histories prior to participation. Upon recruitment, small group informational sessions were held to introduce each student to methods of proper execution of a clinical trial. Topics included recruitment, informed consent, HIPAA, and health history. Aspects of proper clinical research procedures were re-enforced on an individual basis during each evaluation. Participants were given an opportunity to ask questions at any time during the study. A fitness evaluation was performed at 4 designated intervals. During this period, the subjects reported their current fitness habits as compared to their habits prior to their participation in the study. An exit survey regarding the educational experience was performed. The survey included a quiz to assess student learning.

*Results:* Fifty-four subjects were retained through the end of the study. At least two of the graduating participants have received job offers in clinical research with biomedical companies; one student felt the experience helped him gain entry into medical school. Participants performed well on the quiz and reported favorably regarding the experience.

*Conclusion:* Training effectiveness was reflected in the exit survey results, job offers and graduate school opportunities for students, and student conduct. Student motivation is reflected in the self reported gain in interest and confidence in clinical research, in the low attrition rate, and in the increased activity levels of all groups.

## Background

Experiential education has been demonstrated to be effective in medical and nursing schools. Haidet et al. introduced and simulated randomized controlled trial in which students participated directly. They recognized that medical students often have trouble appreciating the relative merits and limitations of clinical research design. After participating, students' homework demonstrated a greater depth of understanding, and students reported the experience was enjoyable and stimulating<sup>1</sup>.

Hitchcock and Murphy involved undergraduate students in three phases of research: as research subjects, data collectors, and analysts in a faculty study focusing on health perceptions of baccalaureate nursing students. The project enabled the students to master the research content, generated high student interest, increased student comfort level with the research process while fostering positive attitudes toward nursing research<sup>2</sup>.

In biomedical engineering, research and clinical care are inextricably linked. Nonetheless, the typical environments in which engineering research and clinical research are conducted are significantly different. To effectively address issues in the clinic, an engineer must be familiar with clinical research design and procedures. Without such training, engineers run the risk of ineffectively applying technology due to underestimates of patient compliance, physiologic variation among subjects, complex physiologic interrelationships in an individual human subject, human error, and other performance limitations imparted in a clinical research environment.

Opportunities for undergraduate biomedical engineering students to participate in clinical research are limited, and in most cases, offer only individual training. Research opportunities usually involve mentoring and it is difficult for faculty to extend themselves beyond one or a handful of students. Labs are usually equipped with facilities designed for use by only a few researchers and often require substantial training and this too, contributes to limiting the amount of students who can participate in research. As a result, most students who participate in clinical research are graduate students, and opportunities for undergraduate participation in clinical research are generally scarce.

It is particularly challenging to offer a clinical experience to students in engineering schools that do not have medical school affiliations. It was hypothesized that a motivating experiential education research project, in the context of a human clinical trial, could be conducted at an engineering school. The focus of the investigation involves the prevention of obesity, clearly an educational challenge in and of itself. This topic was selected primarily to enable the design and implementation of an effective clinical experience in a research environment that does not contain resources that are typically limited to a medical school. Furthermore it was selected so that researchers required only medical supervision and training, but did not require a medical license or other formal clinical qualifications.

In addition the subject test protocol was designed so that any student who desired to participate may do so after medical clearance. An exercise test protocol that followed previous research, and that was not overly strenuous was selected. This ensured that the protocol was safe, and that subject compliance would be as high as possible.

Finally, though a worthy exercise in clinical training, we selected the topic of obesity because it is a subject that has many unmet needs and where the proper clinical application of biomedical technology would be useful<sup>3</sup>. A properly designed study that addresses issues in obesity provides further merit to warrant the IRB's approval of the study. Students participating in an experiential educational research program regarding obesity prevention could effectively learn about clinical research while enhancing their personal fitness habits.

## Methods

74 undergraduate college students age 18-22 were recruited as volunteer subjects and studied for one year. The clinical trial was designed as an opportunity for many undergraduate students to participate in the clinical research process. It was also designed to compare fitness levels among students who participate in school supervised physical activity as recommended by the American College of Sports Medicine with those who do not. Students were selected to participate in one of three different study groups; each group met differing criteria for physical activity. There was a 'varsity athlete group', a group which took a fitness class that followed the ACSM recommendations for adults, 'the PE intervention group', and a third group that did not participate in school organized activity, the 'monitor only group'.

A fitness evaluation was performed at 4 designated intervals. Each student's physical fitness was evaluated four times during the study, once each at the beginning and end of the spring and fall 2006 semesters. The study period was for one year, from January 2006 to December 2006. The trial was conducted at Stevens Institute of Technology utilizing the Biomedical Engineering Exercise Physiology Lab and Stevens Athletic Center.

The study was reviewed and approved by the Institutional Review Board at Stevens. Informed consent was obtained, and a sports medicine physician screened the health histories prior to participation. A study proposal was prepared to satisfy all legal entities that the research, involving human subjects, would protect the privacy of the subjects, that it would be safe, and that it would be worthy of the use of human subjects.

Six students participated as part time research assistants. The researchers were initially trained and subsequently mentored throughout the study by the Principal Investigator and the Medical Advisor, both of whom were Biomedical Engineering faculty. Five were undergraduates and one was a graduate student. The graduate student performed the role of Investigator, and utilized the body composition data that was collected toward fulfillment of a Biomedical Engineering Masters' thesis. The undergraduate researchers performed data collection and analysis under the direction of the Principal Investigator and the Investigator. They were selected for this role in fulfillment of an undergraduate scholar's research program in which they were required to earn 1 research credit per semester. All researchers contributed to the recruitment effort, clinic and equipment preparation and maintenance, and communication with subjects.

Stevens' students were solicited to volunteer as subjects for the study via administration and IRB approved campus announcements, PE class, and team coaches. (Appendix A) Investigators and researches engaged in a campus wide recruitment campaign, personally delivering an overview

of the study information to small groups of interested students (approximately 10 minutes) during PE class, at the gym, at sports team meetings, and at organized leisure meetings.

A website was established to support this study. It provided background information and contained a description of the program. It also collected contact information from students who wished to register for the study. Note: in accordance with HIPAA (Health Insurance Portability and Accountability Act), no confidential information was collected or published. Interested students were invited to participate in an "information session". (Appendix)

Upon recruitment, small group informational sessions were held to introduce each student to methods of proper execution of a clinical trial. Topics included recruitment, informed consent, HIPAA, and health history. Four separate information sessions were given to accommodate student class and work schedules. Each info session was about 45 minutes long.

At the information session, all students were informed about the study (Appendix), advised that they are not required to participate and that they are free to leave the study at any time, given an informed consent form (Appendix) and a health history form (Appendix) to complete and submit if they desire to participate as a subject in the study. The Principal Investigator reviewed and explained each document, page by page, and answered any questions that arose.

The potential subjects were also given copies of the written questionnaires, and a tentative date for their first evaluation, which was contingent upon their completion of their informed consent and having received clearance to participate by the medical advisor.

Completed Informed Consent forms and Health History questionnaires were collected by the Investigators from subject volunteers. These documents were maintained confidential at all times by the Principal Investigator, and will remain locked in the Principal Investigator's office for 6 years after the beginning of the study, and maintained confidential in accordance with the statements on the Informed Consent form.

All health history forms were reviewed by the medical advisor. The medical advisor or the PI, under the medical advisor's direction, contacted any subjects who indicated a history that might put them at risk. After a confidential discussion, the subjects were advised whether they were cleared to participate, or if they required further evaluation. The subjects either chose to obtain further evaluation or to drop their candidacy.

All "cleared" subjects were asked to undergo a fitness evaluation 4 times during the study: at the beginning and the end of each the Spring 06 and Fall 06 semesters. The evaluation consisted of 2 parts: a Treadmill and Body Composition evaluation and a written survey.

The evaluation consisted of taking non-invasive measurements that could provide useful medical information but yet do not require medical certification on the part of the researchers or use of medical lab facilities. At the 'treadmill station' heart rate, oxygen consumption, CO<sub>2</sub> production, anaerobic threshold, and work were continuously measured in a standard 'gas exchange' exercise test protocol. These data were collected at the 'body composition station': % body fat using both

a bioelectric impedance scale and a handheld device, and also by skin-fold measurement. In addition, resting blood pressure, weight, and height were measured.

The 'Monitor only' and 'Athlete' groups received no further group instruction. However, all participants were given an opportunity to ask questions at any time during the study. The 'PE intervention' group received training from the PE instructor regarding: their individual fitness targets in accordance with ACSM guidelines, how to monitor their performance during the activity, and how to keep a log of their activity.

The PE instructor supervised the 'PE intervention' subjects' activity 1X per week. Other required activity was self monitored. An electronic log was established, via Web CT, for each subject to report their activity performance compared to their individual targets. Participants who successfully completed the intervention in each semester were awarded PE credit, with pre-approval from the PE department.

Aspects of proper clinical research procedures were re-enforced on an individual basis during each evaluation. At the beginning of the study, a baseline evaluation was conducted. The subject was introduced to the evaluation protocols and trained in his roles in the procedures. In subsequent evaluation sessions, the subject was guided as needed.

Each subject was also shown how his personal information was managed to maintain confidentiality. Upon entering the evaluation clinic, each subject was assigned a study identification number. All data recorded, processed, and maintained in the clinic were labeled only with the subject ID number. Only the Investigators maintained a list to cross reference the subject's name with his ID number. It was explained that when not in use, this list was locked in the Principal Investigator's office.

During the 4<sup>th</sup> and final evaluation, an exit survey regarding the educational experience was performed. The exit survey was in two parts, it included a quiz to assess student learning, and a survey to determine how the participation experience influenced the students' sentiments toward clinical research. (Appendix)

During the study, the subjects reported their current fitness habits as compared to their habits prior to their participation in the study. This was prepared to assess the concomitant goal to help motivate students to participate and to improve their fitness habits.

## **Results**

Of the seventy-four who began in the study, fifty-four subjects were retained through the end of the study. Attrition, where identified was attributed to student work schedules, injuries, and relocation. Six students obtained co-operative work assignments which took them out of the area for a semester. Three students left school completely. Two students became injured and could not perform the exercise evaluation. Nine students did not cite a reason for choosing not to complete the study.

Participants performed well on the quiz and reported favorably regarding the experience. 93% to 100% of subjects responded affirmatively to questions that asked whether they felt their participation in the project provided learning and motivational benefits. A summary of the scores from the exit quiz is shown in the table below. A detailed tabulation is presented in Appendix G.

Raw score	Score %	n	n %
7	100	19	35
6	85	14	26
5	71	10	19
4	Fail	8	15
3	Fail	2	6

*Table 1: Ranked results from 'Quiz', Part I of 'Exit Survey'*

At least two of the graduating participants have received job offers in clinical research with biomedical companies, and attribute their success in obtaining that job to their participation in the project. One student felt the experience helped him gain entry into medical school.

Subjects reported upon their fitness habits during the study, compared to their habits prior to participating in the study.

	PE	Athletes	Monitor Only
More active now	82%	27%	29%

*Table 2: Percentage of subjects in each group who report to be more active in while in the study, compared to prior to joining the project.*

## Discussion

### *Learning effectiveness*

Based upon student performance in the Exit Quiz, "Part I", the project was a successful learning experience. A majority of students scored very well on the quiz. Using a traditional grading scale, 79% of the students "passed" the quiz, while 61% scored 85% or better, and 35% of students obtained a perfect score. All of the student researchers obtained a perfect score. All but four students reported that they learned something about the clinical trial process by participating in the project.

### *Motivation effectiveness*

Just as important to the success of the project was student interest and motivation generated by their participation. Every student-subject reported that their experience in this project stimulated their interest in clinical research.

Likewise, every student-subject reported that the project helped them to gain confidence in their grasp of the clinical research process. This is an important factor for biomedical engineers who must interact with clinicians. A clinical environment can be intimidating to anyone who has not

had such an experience. Enhancing biomedical engineers' comfort level with the clinic is crucial to their ability to view the clinic as a necessary and integral component to the research process, rather than an independent component or deterrent.

### *Jobs and medical school*

Three students reported that their experience from this project lead to their attainment of a job or medical school acceptance. The jobs included 'surgical clinical representative' and 'clinical research associate' for medical device companies. Specific reasons cited included having provided them with a "competitive edge", and having provided them with specific experience needed to perform the job. One student identified the experience as having 'enlightened' as to the type of career opportunity he desired to pursue.

### *Attrition/ retention*

Because student participation was on a volunteer basis, we presume that student retention correlates well to student interest level. 54 retained out of 74 is 73% retention, which is reasonably good, especially given that student participation in the project was completely on a volunteer basis.

Furthermore, it is important to consider that the attrition of 20 students included 11 students who expressed a desire to complete the study but who could not for logistical reasons. We can assume that the other 9 students dropped out due to lack of interest. Re-examining student retention based upon those who had the ability to complete the study, we then can show that the practical retention is 54/63, which is 86%.

### *Student-subject conduct*

Students appeared to gain good familiarity with the process during the course of the trial. During their first visit, most students asked many questions, and required detailed guidance throughout the evaluation. In the subsequent visits, students were prepared and well anticipated all the steps in the evaluation process.

For example, in the first visit, very few students knew their subject number, and the researchers were required to look it up. The researchers explained the reason for needing a subject number. In the following visits, student subjects arrived at the clinic and knew their number. On the cover page of the written surveys, they stopped writing their name or student ID number, and began writing their subject number only.

Other aspects of their conduct demonstrated that students gained familiarity with biomedical research. In the first visit, they had to be told to take their socks off to step on the impedance scale. In each case, the researchers explained why a measurement must be taken in bare feet. In subsequent visits, the students did not require instructions to remove their socks. Similarly, they were dressed more appropriately for the skin-fold measurement assessment.



### *Student FAQ's and comments*

As mentioned, many students asked questions during their evaluation. They asked more questions during their first evaluation. They also tended to ask more questions of their peers, i.e. student researchers. When faculty researchers were presented, they had a greater tendency to simply follow instructions.

The majority of questions were about why researchers were taking certain measurements. They seemed to have an appreciation for the need to take their height, weight, and blood pressure. Intuitively, they also appeared to understand the need to record data while they performed a graded exercise protocol, and none questioned the need to monitor their heart rate during the treadmill test.

Most frequently, students asked researchers why they were taking skin-fold measurements. Researchers explained that the subject's % body fat could be determined by collecting skin-fold measurement from the specified locations. Having been told that researchers were measuring their body composition with different techniques, the next most frequent question was "how does the equipment work?", while they were using the bioelectric impedance devices. Researchers explained that the body is conductive, and the conductivity of fat is different than muscle.

We had anticipated that students would want to know why they had to wear a mask with special wires attached. During the first evaluation, researchers provided an explanation to each subject while they demonstrated the wearing of the mask and assisted the subject to fit the gear properly. Questions related to that set-up were individually addressed at that time.

Often, student subjects inquired about how are their results compared to others in the study. Researchers explained that every individual's results are private, re-enforcing HIPAA rules. Subjects were told that they would learn the results of the study after the data is reviewed and published, and that they could compare their individual results to the published results at that time.

Many students remarked that the written questionnaire was the hardest part of the evaluation. They found it difficult to recall what they ate and what activities they performed in the past few days. Several students asked why they needed to answer the questionnaire. Researchers explained that the questions helped to provide an accurate picture of their lifestyle with regard to their eating and activity habits. In the exit survey, most students, 81%, agreed that this method was indeed a better way to collect diet and activity history than to ask them for such information directly. This was good training for the student-subjects in the use of specialized surveys as tools.

### *Topic of interest*

Obesity was selected as a research topic to address multiple objectives that would contribute to the success of this project. First, it was important to design a project that could be conducted without medical facilities and labs. If the project was to require even very common human physiologic information such as urine or blood analysis, or images such as x-ray, it could not be

conducted at this school. It was determined that a fitness assessment could provide physiologic data useful toward understanding obesity, and still not need to be conducted with medical lab resources.

Secondly, the level of skill, training, and authority necessary to collect data such as blood pressure, heart rate, body composition, respiratory gas exchange, and written surveys are commensurate with those found in an engineering school and among engineering students. Likewise, the type of equipment and costs associated with collection of such data fit the engineering school research model.

Thirdly, we desired to involve as many students as possible in the study. This study was designed so that any student could participate as a subject. It was safe and feasible for large number of students to participate and comply. A non-exhaustive test protocol was selected so that even students who are not willing to push themselves physically would be willing to participate as subjects.

Next, this topic enabled us to demonstrate some good examples of biomedical engineering via the application of technology to assess physiologic conditions, providing a valuable experience in biomedical research. Students gained exposure to biomedical technologies such as spirometry, and bioelectrical impedance, and they saw how data such as skin-fold, height, weight, blood pressure and gas exchange data could be correlated to physiologic status.

Finally, obesity is a current topic of large public concern with many biomedical engineering needs<sup>3</sup>. For these reasons, we felt as though this topic would be of interest to many students, providing added motivation to participate and enjoy this project. In addition we believed that any personal motivation a student obtained to improve his fitness would be an added benefit to the student and further motivate his participation in the project.

#### *Fitness results support student motivation*

As educators, we recognize that by providing personal relevance of subject matter to students, they are more effectively engaged. Students in all categories reported to have improved their fitness behavior, even though only one group participated in the intervention. Clearly, the students recognized the topic of obesity as one of interest and of personal value. Students were personally motivated to participate in the study.

### **Conclusion**

Student participation in a clinical research project is a very effective teaching tool; it provides good training and motivation. Training effectiveness was reflected in the exit quiz results, job offers to students, and student conduct. Student motivation was very high, and is reflected in the exit survey where 100% of the subjects reported that the project increased their interest and personal confidence in the clinical trial process. Motivation was further demonstrated by the low attrition rate and in the increased activity levels of all groups.

## **Acknowledgements**

The authors would like to express their deep gratitude to the research team for their assistance and dedication: Board Certified Sports Medicine physician Angela Gagliardi, MD, graduate student Investigator Justyna Majdanska, and undergraduate student researchers Esther Rodriguez, Chris McGreevy, Leigh Shahbazian, Chris Beccia, and Ryan Stellar.

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## **APPENDIX A: RECRUITMENT ANNOUNCEMENT**

### **Be Part of an Exciting New Research Project in Sports Medicine**

You can learn about how to conduct research involving human subjects, first-hand! If you are planning a career in health sciences, this is an invaluable opportunity.

The Biomedical Engineering Program and the PE Department @ Stevens are launching a research program in Sports Medicine, and you can participate.

You can be a research subject and learn about the research process while you participate. The study will last for about a year. If you become a subject, you will take a fitness test in the state-of-the-art Biomedical Engineering Labs at the beginning and end of the Spring 2006 and Fall 2006 semesters. All fitness tests are non-invasive, and all individual information will be kept confidential.

The study will observe the fitness of student groups with different exercise habits. You can choose to join a group that is most appropriate for you.

One of the study groups will take fitness class, and can earn 2 PE credits for each semester of participation.

For more information, see the website:

<http://www.edu/biomedshred>

To sign up today, contact:

Justyna Majdanska: [jmajdans@.edu](mailto:jmajdans@.edu)  
Or Professor Hazelwood

## APPENDIX B: INFO SESSION

Re: Sports Medicine Research Launch!

Hey Gang,

Welcome back to Stevens! We hope you had a great holiday break and that you are ready for a very exciting and rewarding semester.

Thanks for volunteering to be a subject in the "Biomed Shred" fitness project. Your participation puts you into the elite class of charter membership on the Sports Medicine Research Team. More importantly, your help in this project should enable us to develop some very important information that could potentially improve the health and welfare of hundreds of thousands of people in the future. We sincerely appreciate your dedication to this effort.

The first and VERY IMPORTANT step in this program is for you to attend an info session. We have scheduled four info sessions and ask that you **attend one** of the sessions. You must attend an info session in order to participate. During the session, we will explain the program in more detail, so that you know exactly what to expect. Also, we will take care of scheduling you for your individual fitness evaluation, as well as handle other official paperwork that is required with this type of research project. We really hope that one of these sessions is convenient for you.

*Note: If you have signed-up for the Biomed Shred PE class, you should attend the Friday, Jan. 20<sup>th</sup> info session in the Schaefer gym @ 11:30 AM. If you have a conflict, please attend one of the other sessions, and identify yourself as a PE class participant. We need to inform you of few special instructions for PE participants.*

Here's the schedule and location for each session:

- **Wed Jan 18th @ 3:30** to 4:30 PM in McLean Basement (BME LAB)
- **Fri Jan 20th @ 3:00** to 4:00 PM in Stevens Athletic Center Conference Room (3<sup>rd</sup> Floor)
- **Tues Jan 24th @ 6:30** to 7:30 PM in McLean Basement (BME LAB)
- **PE participants only: Fri. Jan 20<sup>th</sup> @ 11:30AM** Schaefer gym

Please attend one of these sessions. If, for some reason, you cannot attend a session, please notify us immediately.

We are certain this will be fun and rewarding. On behalf of Stevens and the Biomedical Sports Medicine Research Program, thank you!

Welcome to the Sports Medicine Research Team!  
Professor Hazelwood

Contact info:

Professor Hazelwood or

Justyna Majdanska: [jmajdans@stevens.edu](mailto:jmajdans@stevens.edu)

## APPENDIX C: COVER SHEET OF INFO PACKAGE

### Biomed Shred Fitness Research Project

Welcome to this exciting project! Your participation is very important to this project, to Stevens, and will generate results that could be very critical to the health of your entire generation, worldwide. The success of this project will be due to your dedication. It is very important that you take this commitment seriously, so that the project can be completed.

In addition to your contribution, this is an opportunity for you to learn about fitness and the clinical research process. Please feel free to ask questions at any time.

We are certain you will have fun and learn a lot!

**You are scheduled for the fitness test on \_\_\_\_\_ @ \_\_\_\_\_.**

You should allow 1 hour to complete the test. Note that the test will require that you are active for a period of time, but it is not designed to be exhaustive. The active portion of the test will vary by individual, but we expect it to last between 15 and 25 minutes for most students.

#### **What to wear:**

Sneakers that you can walk in and loose, comfortable active clothing. We recommend you wear a short sleeve T-shirt or a tank top, with warmer layers (that can be removed) over it. You can wear either shorts or sweatpants.

If, for any reason, you cannot make it, please **IMMEDIATELY** contact:

Professor Hazelwood

Or

Justyna Majdanska, [jmajdans@stevens.edu](mailto:jmajdans@stevens.edu)

and arrange to re-schedule. ***It is very important that you notify us if you cannot make it to your appointment; “no shows” will cost us a lot of invested time and resources.***

It is because of dedicated people like you—who care about helping to make the future better by participating in research—that enables good research to produce results that contribute to improving the quality of life of hundreds of thousands of people. On behalf of humankind, we thank you for your participation and dedication.

Thank you,

Professor Hazelwood  
Biomedical Engineering

## APPENDIX D: INFORMED CONSENT

**Principal Investigator: Vikki Hazelwood**

**Investigator: Justyna Majdanska**

**Medical Advisor: Angela Gagliardi, MD Board Certified in Pediatrics & Sports Medicine**

INFORMED CONSENT FORM TO PARTICIPATE AND AUTHORIZATION FOR RESEARCH

### **TITLE OF RESEARCH:**

A Controlled Evaluation of the Relationship Between Exercise Habits and the Fitness of College Students

### **A. PURPOSE OF THE STUDY:**

You are being asked to volunteer in a research study. This consent/authorization form includes information about this study.

The purpose of this study is to compare fitness levels among college students who participate in school supervised physical activity as recommended by the American College of Sports Medicine (ACSM) with those who do not. It is expected that students who participate in school supervised activity will be better able to maintain or improve their fitness level compared to those who do not.

You are being asked to participate in this study because you are a college student, and are between 18 and 22 years of age.

### **B. SUBJECT PARTICIPATION:**

We estimate that the following number of subjects will enroll in this study:  
At this site: 100                      Total at all sites: 100

SUBJECT PARTICIPATION:

- ☐ Inpatient
- ☒ Healthy Subjects
- ☐ Outpatient

You will be asked to undergo a fitness evaluation 4 times during the study: at the beginning and the end of each the Spring 06 and Fall 06 semesters. The evaluation will consist of 2 parts: a fitness test using a treadmill, and a Sports Activity and Nutrition Survey.

Each of these visits will take the following amount of time: one half hour

### **C. DESCRIPTION OF THE RESEARCH:**

You will be assigned to one of three groups:

- a. Varsity athlete
- b. Monitor only (non-varsity athlete).
- c. "Biomed Shred" PE class participant

Thirty students will be assigned to each group.

The 'varsity athlete group' and the 'monitor only group' will receive no further instruction other than to return for the periodic evaluations. Students will not be involved in other weight-control or exercise programs, and will not be restricted in their physical activity.

The "Biomed Shred" PE class participant group' will receive training from the investigators and/or PE instructors regarding their individual fitness targets in accordance with American College of Sports Medicine guidelines, how to monitor their performance during the activity, and how to keep a log of their activity. The PE instructor or Investigator will supervise the subjects' activity 1X per week. Other required activity is self monitored.

The study will consist of 5 steps, performed in 5 Visits

#### **Visit #1**

**Screening:** You will complete a health history form (Appendix A-1) that will reviewed by Dr. Gagliardi. You will also complete a questionnaire about your physical activity and nutrition (Appendix A-2). Dr. Gagliardi will evaluate your medical history to determine whether it is safe for you to participate in this study. There are certain medical reasons, for example, uncontrolled asthma or hypertrophic cardiomyopathy, for which you would be excluded. If Dr. Gagliardi determines that you should not participate for medical reasons, she will explain it to you. This Informed Consent Form will be signed. You will be assigned to a group.

#### **Varsity Athlete Group:**

If you are assigned to the Varsity athlete group, you will receive no further instruction other than to return for periodic evaluations.

#### **Monitor only (non-varsity athlete)Group:**

If you are assigned to the Monitor Only Group, you will receive no further instruction other than to return for periodic evaluations.



### **"Biomed Shred" PE Class Participant Group:**

You will receive training from the investigators and/or PE instructors regarding:

- a. your individual fitness targets in accordance with ACSM guidelines
  - i. strength
  - ii. aerobic activity
- b. how to monitor your performance during the activity
- c. how to keep a log of your activity

An electronic log will be established, via Web CT, for each subject to report their activity performance compared to their individual targets. The Investigator and/or PE instructor will supervise your activity once a week. Other required activity is self monitored.

### **Visit #2**

#### **Fitness Evaluation:**

The evaluation will consist of 2 parts:

1. *Fitness test:* You will perform a cardiovascular fitness test on a motor-driven treadmill. The exercise level will begin at a level you can easily accomplish and will be advanced in stages depending on your fitness level. We may stop the test at any time because of signs of fatigue or you may stop when you wish because of personal feelings of fatigue or discomfort.

The following fitness criteria will be assessed:

- Weight will be assessed with a balance scale
- Height will be assessed with a stadiometer.
- Blood Pressure
- Heart Rate
- Hemoglobin saturation via non-invasive pulse oximetry
- Oxygen consumption
- CO<sub>2</sub> production
- Body composition
  - % body fat and % water will be measured by bioelectric impedance
  - % body fat will be measured by skinfold measurement
- Body Mass Index --calculated on the basis of the height and weight data,
- VO<sub>2</sub> max—calculated on the basis of heart rate performance on the treadmill
- Non-invasive Cardiac Output –calculated from oxygen consumption and carbon dioxide production data
- Stroke Volume—calculated from heart rate and cardiac output data

- Peripheral resistance--calculated from blood pressure and hemoglobin data

2. You will be asked to fill out a *Physical Activity and Nutrition Questionnaire* (Appendix A-2).

**Visit #3**

**Fitness Evaluation (same as above)**

**Visit #4**

**Fitness Evaluation (same as above)**

**Visit #5**

**Fitness Evaluation (same as above)**

**D. COSTS/REIMBURSEMENTS:**

Those participating in the **"Biomed Shred" PE Class group** will receive PE credit.

**E. POTENTIAL RISKS AND DISCOMFORTS:**

There exists the possibility of certain changes occurring during the fitness test. They include abnormal blood pressure, fainting, disorder of heart beat, and in rare instances, hear attack, stroke, or death. Every effort will be made to minimize these risks by evaluation of preliminary information relating to your health and fitness and by observations during testing. Emergency equipment and trained personnel are available to deal with unusual situations that may arise.

Information you possess about your health status or previous experiences of unusual feelings with physical effort may affect the safety and value of your exercise test. Your prompt reporting of feelings with effort during the exercise test itself is also of great importance. You are responsible to fully disclose such information when requested by the testing staff.

**F. POTENTIAL BENEFITS:**

The results obtained from participating in any of the three groups may not help an individual at all, but may produce information that helps understand the role of exercise in fitness improvement or maintenance.

## **G. CONFIDENTIALITY:**

Information obtained in this exercise test will be treated as privileged and confidential and will consequently not be released or revealed to any person without your express written consent. However, your fitness evaluation information will be used for research or statistical purposes as long as this does not lead to your identification.

This section of the consent/authorization form describes how your information will be used and shared in this research, and the ways in which Stevens will safeguard your privacy and confidentiality.

If you agree to be in this research program, the study team will ask you to complete a Health History questionnaire. You will also be asked to answer a Physical Activity and Nutrition questionnaire and perform a fitness test on a treadmill. Your answers to the questionnaires and the results of fitness test will be used to complete the research.

This information will be kept in your file, which will be locked in a cabinet in Room 202 in the McLean Building.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB(s) overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of Stevens will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

### Confidentiality of Your Study Information

Your study records include information that identifies you and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. If data from this study are to be published or presented, we will first take out the information that identifies you.

### Retention of Your Study Information

The study results will be kept in your research record for at least six years or until after the study is completed, whichever is longer. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at Stevens.

### Your HIPAA Authorization

A new federal regulation, the federal medical Privacy Rule, has taken effect as required by the Health Insurance Portability and Accountability Act (HIPAA). Under the Privacy Rule, in most cases we must seek your written permission to use or

disclose identifiable health information about you that we use or create [your “protected health information”] in connection with research involving your treatment or medical records. This permission is called an Authorization.

If you sign this form you are giving your Authorization for the uses and sharing of your protected health information described below. You have a right to refuse to sign this form. If you do not sign the form you may not be in the research program.

This Authorization will not expire unless you withdraw it in writing. You have the right to withdraw your authorization at any time, except to the extent that Stevens has already relied upon it or must continue to use your information to complete data analysis or to report data for this study. The procedure for revoking your authorization is described below in Section K.

By signing this form you authorize the use and disclosure of the following information for this research:

- Your medical history
- Your research record
- Observations made during your participation in the research.

By signing this form you authorize the following persons and organizations to receive your protected health information for purposes related to this research:

- The Stevens Department of Biomedical Engineering and the Athletic Department, and including each department’s research staff and medical staff
- Every health care provider who provides services to you in connection with this study
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study’s protocol
- The following research sponsors and the people and companies they use to oversee, administer, or conduct the research: Stevens Institute of Technology
- The United States research regulatory agencies and other foreign regulatory agencies
- The members and staff of the Stevens affiliated Institutional Review Board
- The members and staff of the Stevens affiliated Privacy Board
- Principal Investigator: Vikki Hazelwood
- Investigator: Justyna Majdanska
- Medical Advisor: Angela Gagliardi, MD
- Study Coordinators within the Stevens Biomedical Engineering Department
- Study Coordinators within the Stevens Athletic Center
- Members of the Research Team
- Data Safety Monitoring Board/Clinical Events Committee, on need to know basis

If any of the companies or institutions listed above merges or is sold during the course of this research, your Authorization will cover uses and disclosures of your protected health information to the new company or institution that assumes responsibility for the research.

Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule, the information is no longer protected by the Privacy Rule and may be subject to redisclosure by the recipient.

#### **H. COMPENSATION/TREATMENT IN THE EVENT OF INJURY:**

All forms of medical (or mental health) diagnosis and treatment – whether routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that we do not know about. In spite of all precautions, you might develop medical complications from being in this study.

If you sustain any injury during the course of the research or experience any side effect to a study procedure, please contact the Principal Investigator Vikki Hazelwood at the following telephone number 201-21-65051. If such complications arise, the investigator will assist you in obtaining appropriate medical treatment but this study does not provide financial assistance for medical or other injury-related costs.

You assume all risks this study, and release and hold harmless Stevens Institute of Technology, and their agents and employees, from any and all health claims, suits, losses, or causes of action for damages, for injury or death, including claims for negligence, arising out of or related to my participation in the fitness assessments.

#### **I. VOLUNTARY PARTICIPATION AND AUTHORIZATION:**

Your decision as to whether or not to take part in this study is completely voluntary (of your free will).

You will be told of any significant new findings developed during the course of the research that may influence your willingness to continue to participate in the research.

Your decision as to whether to give your Authorization for the use and disclosure of your protected health information for this study is also completely voluntary; however, if you decline to give your Authorization or if you withdraw your Authorization you may not participate in the study.

This will not affect your grade in PE or your academic evaluation while a student at Stevens.

#### **J. WITHDRAWAL FROM THE STUDY AND/OR WITHDRAWAL OF AUTHORIZATION:**

If you decide to take part in the study, you may withdraw from participation at any time without penalty. You may also withdraw your Authorization for us to use or disclose your protected health information for the study. If you do decide to withdraw your consent, we ask that you contact Vikki Hazelwood in writing and let her know that you are withdrawing from the study. Her mailing address is  
BME Department  
Castle Point on Hudson  
Hoboken, NJ 07030

If you wish to withdraw your Authorization as well as your consent to be in the study, you must contact Vikki Hazelwood in writing. Remember that withdrawing your Authorization only affects uses and sharing of information after your written request has been received, and you may not withdraw your Authorization for uses or disclosures that we have previously made or must continue to make to complete analyses or report data from the research.

The Principal Investigator or another member of the study team will discuss with you any considerations involved in discontinuing your participation in the study. You will be told how to withdraw from the study and may be asked to return for a final check-up.

The study doctor may also decide to withdraw you from the study for certain reasons. Some possible reasons for withdrawing a subject from the study would be worsening health or other conditions that might make it harmful for you.

#### **K. CONTACT PERSON(S):**

For further information about your rights as a research subject, or if you are not satisfied with the manner in which this study is being conducted and would like to discuss your participation with an institutional representative who is not part of this study, please contact the Administrator, Institutional Board of Research Associates, Telephone No. 201-216-5051

If you have any questions or sustain any injury during the course of the research or experience any adverse reaction to a study procedure, please contact the Principal Investigator  
Vikki Hazelwood at the following telephone number 201216-5051

**AGREEMENT TO PARTICIPATE AND AUTHORIZATION FOR THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION:**

Part of the consent process includes your Authorization to use Protected Health Information for the purposes of this study, as described above. If you do not want to authorize the use of this PHI, you should not agree to be in this study.

☐ I have read this consent form  
or  
☐ it was read to me by: \_\_\_\_\_.

Any questions I had were answered by: \_\_\_\_\_.

I ☐ am ☐ am not participating in another research project at this time.  
(If yes, you should discuss this with your study doctor.)

I voluntarily agree to participate in this research program at:

☐ \_\_\_\_\_

I understand that I am entitled to and will be given a copy of this signed Consent/Authorization Form.

By signing this Consent/Authorization form, I give my Authorization for the uses and disclosures of my protected health information as described above.

**WHEN THE SUBJECT IS AN ADULT:**

\* For subjects who may not be capable of providing informed consent, the signature of a legal representative is required. For a valid HIPAA authorization, the "personal representative" must have authority under state law to make health care decisions for the subject.

\_\_\_\_\_  
Print Name of Participant  
or Legal Representative\*

\_\_\_\_\_/\_\_\_\_\_  
Signature of Participant      Date  
or Legal Representative\*

\_\_\_\_\_  
Print Name of Person

\_\_\_\_\_/\_\_\_\_\_  
Signature of Person      Date

## Obtaining Consent

## Obtaining Consent

[Use this section only when a witness is required.]

\*\* When the elements of informed consent are presented orally to the subject or representative, a witness to the oral presentation is required. [NOTE: it is unclear whether HIPAA authorization may be presented orally – this might require an IRB waiver to permit alteration of the form of authorization]

\_\_\_\_\_  
Print Name of Witness\*\*

\_\_\_\_\_  
Signature of Witness\*\*

/\_\_\_\_\_  
Date



# APPENDIX E: HEALTH HISTORY FORM

## PREPARTICIPATION PHYSICAL EVALUATION -- MEDICAL HISTORY

REVISED 10-14-02

This **MEDICAL HISTORY FORM** must be completed *annually* by parent (or guardian) and student in order for the student to participate in athletic activities. These questions are designed to determine if the student has developed any condition which would make it hazardous to participate in an athletic event.

Student's Name: \_\_\_\_\_ Sex \_\_\_\_\_ Age \_\_\_\_\_ Date of Birth \_\_\_\_\_

Address \_\_\_\_\_ Phone \_\_\_\_\_

Grade \_\_\_\_\_ School \_\_\_\_\_

Personal Physician \_\_\_\_\_ Phone \_\_\_\_\_

In case of emergency, contact:

Name \_\_\_\_\_ Relationship \_\_\_\_\_ Phone (H) \_\_\_\_\_ (W) \_\_\_\_\_

**Explain "Yes" answers below. Circle questions you don't know the answers to. Any Yes answer to questions 1, 2, 7, 11, or 17 requires a physical exam using the Preparticipation Physical Evaluation Form on the reverse side.**

1. Have you had a medical illness or injury since your last check up or sports physical?	Yes <input type="checkbox"/> No <input type="checkbox"/>	10. Have you had any problems with your eyes or vision?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2. Have you been hospitalized overnight in the past year?	<input type="checkbox"/> <input type="checkbox"/>	11. Are you missing any paired organs?	<input type="checkbox"/> <input type="checkbox"/>
Have you had surgery in the past year?	<input type="checkbox"/> <input type="checkbox"/>	12. Do you use any special protective or corrective equipment or devices that aren't usually used for your sport or position (for example, knee brace, special neck roll, foot orthotics, retainer on your teeth, hearing aid)?	<input type="checkbox"/> <input type="checkbox"/>
3. Are you currently taking any prescription or non-prescription (over-the-counter) medication or pills or using an inhaler?	<input type="checkbox"/> <input type="checkbox"/>	13. Have you ever had a sprain, strain, or swelling after injury?	<input type="checkbox"/> <input type="checkbox"/>
4. Do you have any allergies (for example, to pollen, medicine, food, or stinging insects)?	<input type="checkbox"/> <input type="checkbox"/>	Have you broken or fractured any bones or dislocated any joints?	<input type="checkbox"/> <input type="checkbox"/>
5. Have you ever passed out during or after exercise?	<input type="checkbox"/> <input type="checkbox"/>	Have you had any other problems with pain or swelling in muscles, tendons, bones, or joints?	<input type="checkbox"/> <input type="checkbox"/>
Have you ever been dizzy during or after exercise?	<input type="checkbox"/> <input type="checkbox"/>	If yes, check appropriate box and explain below.	
Have you ever had chest pain during or after exercise?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Head <input type="checkbox"/> Elbow <input type="checkbox"/> Hip	
Do you get tired more quickly than your friends do during exercise?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Neck <input type="checkbox"/> Forearm <input type="checkbox"/> Thigh	
Have you ever had racing of your heart or skipped heartbeats?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Back <input type="checkbox"/> Wrist <input type="checkbox"/> Knee	
Have you had high blood pressure or high cholesterol?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Chest <input type="checkbox"/> Hand <input type="checkbox"/> Shin/Calf	
Have you ever been told you have a heart murmur?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Shoulder <input type="checkbox"/> Finger <input type="checkbox"/> Ankle	
Has any family member or relative died of heart problems or of sudden unexpected death before age 50?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Upper Arm <input type="checkbox"/> Foot	
Has any family member been diagnosed with enlarged heart, hypertrophic cardiomyopathy, long QT syndrome, Marfan's syndrome, or abnormal heart rhythm?	<input type="checkbox"/> <input type="checkbox"/>	14. Do you want to weigh more or less than you do now?	<input type="checkbox"/> <input type="checkbox"/>
Have you had a severe viral infection (for example, myocarditis or mononucleosis) within the last month?	<input type="checkbox"/> <input type="checkbox"/>	Do you lose weight regularly to meet weight requirements for your sport?	<input type="checkbox"/> <input type="checkbox"/>
Has a physician ever denied or restricted your participation in sports for any heart problems?	<input type="checkbox"/> <input type="checkbox"/>	15. Do you feel stressed out?	<input type="checkbox"/> <input type="checkbox"/>
6. Do you have any current skin problems (for example, itching, rashes, acne, warts, fungus, or blisters)?	<input type="checkbox"/> <input type="checkbox"/>	16. Record the dates of your most recent immunizations (shots) for:	<input type="checkbox"/> <input type="checkbox"/>
7. Have you ever had a head injury or concussion?	<input type="checkbox"/> <input type="checkbox"/>	Tetanus _____ Measles _____	
Have you ever been knocked out, become unconscious, or lost your memory?	<input type="checkbox"/> <input type="checkbox"/>	Hepatitis B _____ Chickenpox _____	
If yes, how many times? _____ When was the last concussion? _____		17. Are you under a doctor's care?	<input type="checkbox"/> <input type="checkbox"/>
How severe was each one? (Explain below)		<b>Females Only</b>	
Have you ever had a seizure?	<input type="checkbox"/> <input type="checkbox"/>	18. When was your first menstrual period?	_____
Do you have frequent or severe headaches?	<input type="checkbox"/> <input type="checkbox"/>	When was your most recent menstrual period?	_____
Have you ever had numbness or tingling in your arms, hands, legs, or feet?	<input type="checkbox"/> <input type="checkbox"/>	How much time do you usually have from the start of one period to the start of another?	_____
Have you ever had a stinger, burner, or pinched nerve?	<input type="checkbox"/> <input type="checkbox"/>	How many periods have you had in the last year?	_____
8. Have you ever become ill from exercising in the heat?	<input type="checkbox"/> <input type="checkbox"/>	What was the longest time between periods in the last year?	_____
9. Have you ever gotten unexpectedly short of breath with exercise?	<input type="checkbox"/> <input type="checkbox"/>	Explain "Yes" answers here: (A "yes" on questions 1, 2, 7, 11 or 17 requires a further medical evaluation which may include a physical examination. Written clearance from a physician, physician assistant, or nurse practitioner is required before any participation in UIL practices, games or matches.)	
Do you cough, wheeze, or have trouble breathing during or after activity?	<input type="checkbox"/> <input type="checkbox"/>		
Do you have asthma?	<input type="checkbox"/> <input type="checkbox"/>		
Do you have seasonal allergies that require medical treatment?	<input type="checkbox"/> <input type="checkbox"/>		

It is understood that even though protective equipment is worn by the athlete, whenever needed, the possibility of an accident still remains. Neither the University Interscholastic League nor the high school assumes any responsibility in case an accident occurs.

If, in the judgment of any representative of the school, the above student should need immediate care and treatment as a result of any injury or sickness, I do hereby request, authorize, and consent to such care and treatment as may be given said student by any physician, trainer, nurse or school representative. I do hereby agree to indemnify and save harmless the school and any school or hospital representative from any claim by any person on account of such care and treatment of said student.

If, between this date and the beginning of athletic competition, any illness or injury should occur that may limit this student's participation, I agree to notify the school authorities of such illness or injury.

To the Parent: ☐ Baseball ☐ Football ☐ Softball ☐ Tennis ☐ Wrestling  
 Check any activity in which this student is allowed to participate. ☐ Basketball ☐ Golf ☐ Swimming & Diving ☐ Track & Field  
☐ Cross Country ☐ Soccer ☐ Team Tennis ☐ Volleyball

I hereby state that, to the best of my knowledge, my answers to the above questions are complete and correct.

Student Signature: \_\_\_\_\_ Parent/Guardian Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## APPENDIX F: EXIT SURVEY

### “Biomed Shred” Research Subject Exit Survey

December 2006

SUBJECT No. \_\_\_\_\_

Study Group: M   A   PE

(Circle one)

*We would like to know what you have learned with respect to the clinical trial process. Refusal to respond to this exit survey will not harm an individual's relationship with the investigators or the University*

#### Part I

1. Which of the following **WAS NOT** part of your informed consent agreement?
  - a. key facts about the clinical trial
  - b. the purpose, duration, required procedures, and key contacts
  - c. a contract requiring that I may not withdraw from the study once it starts
2. When must you sign an informed consent agreement?
  - a. Anytime while the study is ongoing
  - b. After I understand my role as a subject in the trial and before I participate as a subject
  - c. As soon as I am recruited and before I know the details of the study
3. It would have been OK for Stevens to pay me to be a volunteer in this study, but they just didn't have the money.
  - a. True
  - b. False
4. The researchers referred to me by subject number because (pick the **BEST** reason)
  - a. It was easier for them than remembering my name
  - b. They are required to keep my identity secret in their reports
  - c. Their computer program only used numbers, not names
5. Which of the following statements about an [Institutional Review Board](#) (IRB) **IS FALSE?**
  - a. The IRB makes sure the risks are as low as possible and are worth any potential benefits.
  - b. The IRB is not required for research involving human subjects in an academic setting
  - c. The IRB initially approves and periodically reviews the research
6. Which of the following statements about including a subject's medical history is **TRUE?**
  - a. The entire research team reviewed it to compare it to my performance in order to interpret the data
  - b. The doctor needed to be sure that it was safe for me to perform the exercises
  - c. The Investigators needed to share my information with anyone who asked for it
7. The reason why the Investigators could not tell me how my measurements compared to other individuals was because of HIPAA (Health Insurance Portability and Accountability Act)
  - a. True
  - b. False

## Part II

1. Do you feel that you learned something about the clinical trial process by participating in Biomed Shred?
  - a. Yes
  - b. No
2. Since you joined Biomed Shred, have you obtained a job/ co-op/ internship that involve or are related to clinical trials?
  - a. Yes
    - i. Type of job/co-op/internship \_\_\_\_\_
  - b. No
3. If you answered 'Yes' to #2, please answer this question, (otherwise please skip to next question.) Do you feel that your participation in Biomed Shred helped you get that job?
  - a. Yes
  - b. No
4. Would you be more interested in participating in another research project or conducting your own research, now that you've experienced Biomed Shred?
  - a. Yes
  - b. No
5. Do you feel like Biomed Shred helped you to gain confidence in understanding or participating in future research projects?
  - a. Yes
  - b. No
6. Do you believe that the Lifestyle questionnaire (about your eating and activity habits) better captured your true habits than if we had asked you to simply write down what you ate and what activities you did on a sheet of paper?
  - a. Yes
  - b. No

Thank you for your very important contribution to this work!

## APPENDIX G: EXIT SURVEY RESULTS-DETAIL

		Evaluation #4 Exit Survey Results					
		Subject Respondents:					
<b>Answer #</b>		<b>Monitor</b>		<b>PE Intervention</b>		<b>Athlete</b>	
		<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
		<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Part I		<b>20</b>		<b>21</b>		<b>13</b>	
1	a	1	5%	2	10%	1	8%
	b	1	5%	0	0%	1	8%
	c	18	90%	19	90%	10	77%
2	a	0	0%	0	0%	0	0%
	b	20	100%	19	90%	13	100%
	c	0	0%	1	5%	0	0%
3	a	4	20%	5	24%	4	31%
	b	16	80%	16	76%	9	69%
4	a	0	0%	0	0%	2	15%
	b	19	95%	18	86%	11	85%
	c	1	5%	1	5%	0	0%
5	a	0	0%	1	5%	3	23%
	b	16	80%	15	71%	9	69%
	c	3	15%	5	24%	1	8%
6	a	2	10%	5	24%	0	0%
	b	18	90%	16	76%	13	100%
	c	0	0%	0	0%	0	0%
7	a	16	80%	15	71%	12	92%
	b	4	20%	6	29%	1	8%
Part II							
1	a	18		19		13	
	b	2		2		0	
2	a	1		1		4	
	b	2		20		9	
3	a	0		0		3	
	b	1		1		1	
4	a	20		21		13	
	b	0		0		0	
5	a	20		21		13	
	b	0		0		0	
6	a	15		18		11	
	b	5		3		2	
Correct Score Part I							
100%	All	8		7		4	
85%	6	6		4		4	
71%	5	0		5		5	
Fail	4	4		4		0	
Fail	3	2		1		0	