Protocol Review Number: 16-95
(Assigned by IRB)

University of the Pacific
Institutional Review Board
Human Subjects Activity Review Form

I. Project Information	
Investigator Name:	Mark Morozumi
E-Mail Address:	m_morozumi@u.pacific.edu
College/School:	University of the Pacific
Department:	Health, Exercise & Sport Sciences
If Student, Name of Advisor:	Courtney Jensen, Ph.D.
Advisor Dept:	Health, Exercise & Sport Sciences
Advisor email:	cjensen1@pacific.edu
Other Thesis/Dissertation Committee Members:	
If Student, Expected Graduation Date:	Spring 2018
List all other personnel involved in the data collection/analysis:	
Project Title:	Effects of Academic Stress of Force/Torque Output
Date CITI training completed (include certificate for all personnel involved in the data collection/analysis)	11/09/2015
Review category & number: See pg. 25 in the IRB Manual **(If exempt, attach required cover memo)** If your research involves pre-existing data, please complete the Existing Data Research Review Form only.	Expedited #6
When do you plan to begin this study* (date/year?) *This date should NOT be earlier than your submission date and should allow time for IRB review.	~~December 2015~~ February 2016 M.M.
What is the expected duration of the study?	2 months
Has this project been reviewed by any other IRB? If yes, stop completing this application and contact the IRB administrator to determine whether a Cooperative Agreement can be entered.	no

II. Project Support	
☒ Funded ☐ Unfunded	If funded, list source: Phi Epsilon Kappa
Does any conflict of interest exist between the funding source and the investigator? ☐ Yes ☒ No (refer to Conflict of Interest Policy at: http://web.pacific.edu/x14005.xml	If yes, describe:

Investigator Status (Check one)
☒ Student ☐ Faculty ☐ Administrator ☐ Other_____

Investigator Signature and Certification: In submitting this proposed project and signing below, I certify that:

1) I have read and understand the Investigator's Manual on Research with Human Subjects;
2) I will conduct the research involving human subjects as presented in the protocol and approved by the unit, faculty supervisor (if a student project), and IRB;
3) I will present any proposed modifications in the research to the IRB for review prior to implementation;
4) All conflicts of interest between myself and any funding agencies have been resolved to the satisfaction of the University of the Pacific Office of Sponsored Programs, and,
5) I will report to the IRB any problems or injuries to subjects.

Signed: _____ Date: 1/25/16

Faculty Supervisor Review (if researcher is a student): My signature verifies that:

1) I will supervise this student's research project, and
2) The research complies with federal and University policies regarding protection of human subjects.

Approval: Courtney Jensen Date: 1/25/2016

Unit Review: The signature below verifies that the project:

1) Has been reviewed by the unit, and
2) Complies with federal and University regulations for research with human subjects.

Approval: _____ Date: 1-25-16

Name: J Mark VanNess

Unit reviewer may be: department chair, college dean, or a member of the Institution al Review Board within the researcher's department

INVESTIGATOR: Please provide answers to all of the following questions (attach additional pages as needed).

Applications must be signed, scanned as PDF documents, and submitted by e-mail to the IRB Administrator in Research and Sponsored Programs at osp@pacific.edu.

III. Purpose and Objectives of the Research

Active students and student athletes often are under constant academic stress, as well as physical stress. This academic stress could be affecting the physical performance of student athletes, or be affecting the performance of just regular, physically active students. I want to find out, and potentially prove that physical performance is compromised by stress from the student's classes.

IV. Contribution to, or development of, generalizable knowledge

This can help us better understand how students are affected by stress, especially those who are physically active.

V. Description of Subject Population(s)

A.) Who are the subject groups and how are they being recruited?	University of the Pacific students who regularly engage in physical activity. I am seeking out students with whom I am already acquainted with, and know to be physically active.
B.) What is the maximum # of subjects you will enroll?	15
C.) Are you advertising for subjects? ☐ Yes ☒ No If yes, include a copy of the proposed advertisement.	
D.) What are the criteria for selection and/or exclusion of subjects? (See page 20 in IRB Manual.)	Must be capable of performing the exercise required by the study Must not have any injuries that would preclude their participation Will discover injury history from each participant via a brief screening questionnaire.
E.) If special populations are being used, please justify. (See page 20 in IRB Manual.)	

VI. Activities Involving Human Subjects

A.) Describe the activities involving each subject group described in II.A. Include the expected amount of time subjects will be involved in each activity, and where the activities will be conducted. ATTACH methodology section of your grant proposal, dissertation or thesis.

Participants will be brought in one week before finals week and individually tested on our department's machine, the Cybex Humac Norm, and will be ask to do a hamstring-quadricep isokinetic at 60 degrees per second. The subject's participation should take no more than 5 minutes each.

Then, the week after our school's winter break, I will have the same students come back and re-do the experiment to see the differences between torque output.

I will observe the activity and compile data after both tests.

B.) How will the data be collected? Check all that apply:

- ☐ Questionnaires (**submit a copy**)
- ☐ Interviews (**submit list of questions**)
- ☒ Observances (briefly describe below)

I (along with my faculty advisor) will be supervising the experiment as the students do the force test.

- ☐ Standardized tests (list names of tests, AND attach copy of each test)
- ☐ Other (describe)

VII. Data

A.) How will the data be recorded (notes, tapes, computer files, completed questionnaires or tests, etc.)?

The data will be recorded and stored on a computer in an encrypted file.

B.) Will medical records or other patient data be accessed? Refer to the IRB Investigators Manual for the 18 identifiers listed in HIPAA regulations and a sample HIPAA Authorization

☐ Yes ☒ No

If yes, complete the HIPAA Privacy Rule Questionnaire and provide a copy of the HIPAA Authorization Form that will be used.

C.) Who will have access to the gathered data, and how will confidentiality be maintained *during* the study, *after* the study, and *in reporting* of results?

The primary investigator is the only individual that will have access to the names of the subjects with the data. The rest of the team (at least those who have not done CITI training) will have access to the data with identifiers assigned so that the identities of the subjects remain confidential. The team includes Angie Wei, Stephanie Gee, Voonchi Chia, Nicole Laskosky. They will be analyzing the data along with me to come up with an answer to our research question.

D.) What are the plans for the data after completion of this study (publication/presentation), and *how* and *when* will the data be maintained or destroyed? Describe method(s) of destroying the data, including any audio or visual recordings.

Data will be used in school publications (student run health science journal), as well as presented at a national research conference (Council on Undergraduate Research, held this upcoming year on April 7-9 at the University of North Carolina, Asheville).

The data will be kept for 3 years after the publication and presentation of the results. At that time, all data collected during the experiment will be deleted from the encrypted file off of the primary investigator's computer.

VIII. Benefits, Risks, Costs

A.) What are the potential benefits to humanity?

Students as well as anyone who reads the study will have a better understanding of the correlation between academic stress and physical activity. Hopefully humanity will progress toward an importance put on physical activity and maintaining one's health.

B.) What are the potential benefits to the subjects?

The subjects will have a voice (anonymously) in showing how academic stress affects students.

C.) What compensation, if any, will be offered to the subjects and how will payment be scheduled throughout the study?

D.) Assessment and Description of Risks. See section VIII. In the IRB Manual for descriptions of risks.

1.) What risks to the subject are most likely to be encountered, and at what level?

Type of Risk	Not applicable to this study	Minimal	More than Minimal	Not Sure
Physical	☐	☒	☐	☐
Psychological (emotional, behavioral, etc. – including anxiety)	☒	☐	☐	☐
Sociological (embarrassment, loss of respect of others, labeling a subject in a way that will have negative consequences.)	☐	☒	☐	☐
Loss of confidentiality	☐	☒	☐	☐
Criminal or civil liability	☒	☐	☐	☐
Deception	☒	☐	☐	☐
Economic	☒	☐	☐	☐
Other (explain)		☐	☐	☐

2.) Describe all risks identified in D1. **Include this information in Informed Consent form also.**

Psychological - The individuals in this test should be stressed academically around the time of the first tests, so psychological stress could be an issue, although not the fault of the research study.

Sociological – Subjects may be seen by others while the data are being collected. The lab facility is along a corridor in the main gym.

Physical - If there were to be incorrect form of the activity required, then an injury could potentially, yet very unlikely, be obtained.

Loss of Confidentiality – while doing the test, the subjects could be seen by other students as there are small windows in the doors.

E.) What safeguards will you use to eliminate or minimize each of these risks? If subjects experience adverse reactions, how will they be managed?

The risks in this study are minimal, but in order to eliminate physical risks, I will be supervising (along with my student advisor) to ensure that the subjects are performing the exercise correctly to eliminate the risk of injury. If they are performing incorrectly, we will stop them and correct them. Also, the subjects will be free to discontinue the tests at any time.

In order to avoid sociological risk, the experimenters will shade the windows in the lab in the main gym and use the laboratory facilities when no one else is in the lab.

As far as confidentiality goes, only the PI will have the subject identifiers that link the subject with their code that is used on the data sheet. All data will be kept on a password protected laptop only using assigned identifiers.

The data will be secured by keeping it in an encrypted file on my computer and will be destroyed 3 years after publication.

F.) What are the costs, if any, to the subjects (monetary, time, etc.)?

A loss of 5-10 minutes of their time.

IX. Other Compliance Issues

A.) If this project may be subject to other regulations, such as state or local laws protecting

special populations, or the use of a new drug or device, please identify and discuss.

B.) If this project involves any of the following activities, requiring consideration by another committee, please check:

- ☐ Animal Use and Care
- ☐ Radiation Safety (including use of x-rays, microwaves)
- ☐ Biological Safety (including recombinant DNA, biohazards)
- ☐ Chemical Safety (including hazardous waste materials, chemical carcinogens, flammable, lab safety)

X. Informed Consent

A.) How will the study be explained to the subjects, and by whom?

The informed consent page will be physically given to students and explained in person by myself. They will be reminded their rights and given their own copy so that they may reference it at any time.

B.) Attach informed consent form(s) you will use in the study (refer to Section IX in the Manual).

C.) Indicate rationale for any special conditions relating to informed consent (e.g., request for approval to obtain oral consent or waiver of documentation).

INFORMED CONSENT

Effects of Academic Stress on Force & Torque Output

You are invited to participate in a research study which will involve the use of a machine called "Cybex Humac Norm," in which we will be testing . My name is Mark Morozumi, and I am a student at the University of the Pacific, in the department of Health, Exercise and Sport Sciences. You were selected as a possible participant in this study because you are a student at the University of the Pacific and I most likely am directly acquainted with you. We will be testing your ability to exert force while under low academic stress and then higher academic stress.

The purpose of this research is to understand better how academic stress affects college students This study is relevant to not only athletes (whose performance may be affected by academic stress), but also the average, physically active student. If you decide to participate, you will be asked to sit and do a hamstring-quadricep isokinetic at 60 degrees per second. Your participation in this study will last a few minutes for one trial at an agreed upon date where you feel low stress and a few minutes for a second trial around exams, when you are feeling stressed.

There are some possible risks involved for participants. These risks include psychological risks, seeing that you will be stressed around the time of the tests, sociological, as you could potentially be seen by others while performing the tests, physical, as performing the required movements incorrectly could cause injury, and loss of confidentiality, due to the same reasons for sociological risks. These risks are very unlikely to occur, and multiple actions will be taken to minimize the risk during the experiment. For sociological and loss of confidentiality, there will be a shade in front of all windows during the testing, and identifiers used on your name in the data, which will be kept in an encrypted file. For physical, I will be supervising (along with my student advisor) to ensure that you are performing the exercise correctly. There are some benefits to this research, particularly that we will have a better understanding of how academic stress affects force/torque output.

If you have any questions about the research at any time, please call me at 415-686-3444, or contact Courtney Jensen at cjensen1@pacific.edu. If you have any questions about your rights as a participant in a research project please call the Research & Graduate Studies Office, University of the Pacific (209) 946-7367. In the event of a research-related injury, please advise us, and then contact your regular medical provider and bill through your normal insurance carrier.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission. Measures to insure your confidentiality are that all the data and information as well as your name with be kept in a password protected file on my computer. The data obtained will be maintained in a safe, locked location and will be destroyed after a period of three years after the study is completed.

Your participation is entirely voluntary and your decision whether or not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you are free to discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

Your signature below indicates that you have read and understand the information provided above, that you willingly agree to participate, that you may withdraw your consent at any time and discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled, that you

will receive a copy of this form, and that you are not waiving any legal claims, rights or remedies.

If you would like to obtain the results for this study, please contact me for information, or to see where it is published.

You will be offered a copy of this signed form to keep.

Signature	Date
_____	_____

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Mark Morozumi (ID: 5203831)
- **Email:** m_morozumi@u.pacific.edu
- **Institution Affiliation:** University of the Pacific (ID: 2800)
- **Institution Unit:** Health, Exercise, & Sport Sciences

- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 17867588
- **Completion Date:** 11/09/2015
- **Expiration Date:** 11/08/2018
- **Minimum Passing:** 80
- **Reported Score*:** 86

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	11/09/15	3/3 (100%)
History and Ethical Principles - SBE (ID: 490)	11/09/15	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	11/09/15	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	11/09/15	5/5 (100%)
Assessing Risk - SBE (ID: 503)	11/09/15	4/5 (80%)
Informed Consent - SBE (ID: 504)	11/09/15	4/5 (80%)
Privacy and Confidentiality - SBE (ID: 505)	11/09/15	4/5 (80%)
Research with Children - SBE (ID: 507)	11/09/15	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	11/09/15	2/5 (40%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Mark Morozumi (ID: 5203831)
- **Email:** m_morozumi@u.pacific.edu
- **Institution Affiliation:** University of the Pacific (ID: 2800)
- **Institution Unit:** Health, Exercise, & Sport Sciences

- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 17867588
- **Report Date:** 11/09/2015
- **Current Score**:** 86

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethical Principles - SBE (ID: 490)	11/09/15	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	11/09/15	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	11/09/15	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	11/09/15	5/5 (100%)
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COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Courtney Jensen (ID: 1511313)
- **Email:** cjensen1@pacific.edu
- **Institution Affiliation:** University of the Pacific (ID: 2800)
- **Institution Unit:** Health, Exercise, and Sport Sciences

- **Curriculum Group:** Biomedical Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

- **Report ID:** 18542959
- **Completion Date:** 01/29/2016
- **Expiration Date:** 01/28/2019
- **Minimum Passing:** 80
- **Reported Score*:** 93

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	01/29/16	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	12/17/09	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	12/20/09	5/5 (100%)
Informed Consent (ID: 3)	12/21/09	3/4 (75%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	12/26/09	4/4 (100%)
Records-Based Research (ID: 5)	01/29/16	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	12/27/09	2/2 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	01/29/16	4/5 (80%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	01/29/16	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	12/28/09	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	12/28/09	3/3 (100%)
FDA-Regulated Research (ID: 12)	12/29/09	4/5 (80%)
Research and HIPAA Privacy Protections (ID: 14)	12/29/09	1/2 (50%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	01/29/16	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	12/30/09	2/2 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	01/29/16	5/5 (100%)
Cultural Competence in Research (ID: 15166)	01/29/16	4/5 (80%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	01/29/16	3/3 (100%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	01/29/16	3/3 (100%)
Completing the Human Subjects Research (HSR) Course (ID: 15686)	01/29/16	No Quiz

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COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Courtney Jensen (ID: 1511313)
- **Email:** cjensen1@pacific.edu
- **Institution Affiliation:** University of the Pacific (ID: 2800)
- **Institution Unit:** Health, Exercise, and Sport Sciences

- **Curriculum Group:** Biomedical Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in biomedical research with human subjects.

- **Report ID:** 18542959
- **Report Date:** 02/11/2016
- **Current Score**:** 93

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	12/17/09	7/7 (100%)
Informed Consent (ID: 3)	12/21/09	3/4 (75%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	12/26/09	4/4 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	01/29/16	3/3 (100%)
Records-Based Research (ID: 5)	01/29/16	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	12/27/09	2/2 (100%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	01/29/16	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	12/28/09	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	12/28/09	3/3 (100%)
FDA-Regulated Research (ID: 12)	12/29/09	4/5 (80%)
International Studies (ID: 971)	12/29/09	1/1 (100%)
Research and HIPAA Privacy Protections (ID: 14)	12/29/09	1/2 (50%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	01/29/16	4/4 (100%)
Hot Topics (ID: 487)	12/29/09	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	12/30/09	2/2 (100%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	01/29/16	3/3 (100%)
Cultural Competence in Research (ID: 15166)	01/29/16	4/5 (80%)
Avoiding Group Harms - International Research Perspectives (ID: 14081)	01/29/16	3/3 (100%)
Completing the Human Subjects Research (HSR) Course (ID: 15686)	01/29/16	No Quiz
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	12/20/09	5/5 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	01/29/16	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	01/29/16	4/5 (80%)

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