Protocol Review Number: _____
(Assigned by IRB)

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

I. Project Information	
Investigator Name:	Angela D'Souza, Samantha Jamosmos, Angela Nuccio, Cynthia Villalobos
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College/School:	University of the Pacific
Department:	Health, Exercise, and Sport Sciences
If Student, Name of Advisor:	Dr. Courtney Jensen
Advisor Dept:	Health, Exercise, and Sport Sciences
Advisor email:	cjensen1@pacific.edu
Other Thesis/Dissertation Committee Members:	N/A
If Student, Expected Graduation Date:	May 2017
List all other personnel involved in the data collection/analysis:	Cali Van Valkenburg, Certified Kinesio Taping Practitioner (CKTP)
Project Title:	Kinesio Tape: Effect on Force Output
Date CITI training completed (**include certificate** for all personnel involved in the data collection/analysis)	Please see attached PDF below.
Review category & number: See pg. 24 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, category number 4
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 1, 2016
What is the expected duration of the study?	From December 2016 to March 2017

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:
Does any conflict of interest exist between the funding source and the investigator? ☐ Yes ☐ No (refer to Conflict of Interest Policy)	If yes, describe: N/A

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

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

The purpose of this experiment is to investigate whether Kinesio Tape (KT) effects skeletal muscle function and the magnitude muscle force production. In this research, we will be evaluating the effects of Kinesio Tape (KT) on the performance of recreationally active college students aged 18-24.
We will use a Cybex Humac Norm dynamometer system to compare the force output of the dominant leg in three different conditions: 1) A KT application that purportedly inhibits muscle recruitment, 2) a KT application that purportedly facilitates muscle recruitment, and 3) no KT. The KT will be applied by a Certified Kinesio Taping Practitioner. Two surface EMG electrodes will be placed on the subject's skin over the rectus femoris muscle to record the electrical activity produced under the three conditions.

IV. Contribution to, or development of, generalizable knowledge

Conducting this research will develop a person's knowledge on the effects of Kinesio Tape (KT) on force output. Due to the recent increase in KT use, many individuals have been exposed to this tape before. The researchers hope to inform active individuals about the tape's effectiveness in modulating force output. If KT is not effective, individuals can look toward other options for improving performance.

V. Description of Subject Population(s)

A.) Who are the subject groups and how are they being recruited?	The subject group will include 12 males and 12 females aged 18-24 from the University of the Pacific in Stockton, a northern California university. These subjects will be recruited by distributing a survey (in paper format) to members at the university gym. We will be approaching potential participants while standing at the front entrance of the university gym, asking if they are interested in participating in our research on Kinesio Tape. If interested, they will first read and fill out a paper consent form and then a paper survey in person. The potential subject will complete the survey at the tables near the front entrance in a public setting. However, if the participant wishes to fill the survey out in private, they will be allowed to take the survey home and return it to us in person by contacting us via email or telephone. After approximately 55 surveys are filled out, the

	researchers will examine each survey and see who is qualified. If the requirements are met, participants will be selected at random from completed surveys.
B.) What is the maximum # of subjects you will enroll?	The maximum number of subjects enrolled will be 24. We intend to administer the questionnaire to approximately 55 individuals.
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 21 in IRB Manual.)	Participants must have a recreationally active lifestyle and be between ages 18-24. A recreationally active lifestyle will be defined as participating in at least 30 minutes of moderate intensity, physical activity on at least 3 days of the week for at least 3 months. This study will only include cisgender individuals. Participants must not have a current or recent injury that could influence performance.
E.) If special populations are being used, please justify. (See page 49 in IRB Manual.)	N/A

VI. Activities Involving Human Subjects

A.) Describe the activities involving each subject group described in V.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.

To recruit participants, we will be approaching potential participants while standing at the front entrance of the university gym, asking if they are interested in participating in our research on Kinesio Tape. If interested, they will first fill out a paper consent form and then a paper survey in person. The potential subject will complete the survey at the tables near the front entrance in a public setting. However, if the participant wishes to fill the survey out in private, they will be allowed to take the survey home and return it to us in person by contacting us via email or telephone. After approximately 55 surveys are filled out, the researchers will examine each survey and see who is qualified. If the requirements are met, participants will be selected at random from completed surveys.

Once the the subjects have been selected through the questionnaire, they will be scheduled for three visits for the experiment via email or telephone. The experiment will take place at University of the Pacific in the Health, Exercise and Sports, Science (HESP) building in room 118, also known as Main Gym. For each visit, all four of the researchers, the Certified Kinesio Taping Practitioner, and the subject will be present. Subjects will be tested three times on three separate dates on the Cybex machine which is also located in room 118 of the HESP building . The subjects will spend roughly fifteen minutes each session. Subjects will be set up on the Cybex machines according to their body specifications. Subjects will be tested under three conditions at random;

without Kinesio Tape, with Kinesio Tape for muscle facilitation, and with Kinesio Tape for muscle inhibition. Cali Van Valkinburg, a Certified Kinesio Taping Practitioner, will apply the Kinesio Tape in room 118 to each subject before being set up on the Cybex machine. Only the CKTP and the subject will be present in room 118 during the taping process. The placement of the Kinesio Tape will be on the anterior superior iliac spine of the hip bone to the patella of the dominant leg, targeting the rectus femoris muscle. The placement of the EMG electrodes will be on the rectus femoris muscle of the dominant leg.
Subjects will undergo a standardized leg warm up exercise in room 118, then be asked to perform repeated maximal concentric leg extension repetitions to determine force production and EMG activity.

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

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

N/A

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

N/A

☒ Other (describe)

Cybex Humac Norm dynamometer system

VII. Data

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

Data will first be collected through completed questionnaires. Then, once participants have been chosen from the questionnaire, data will be recorded through the Cybex machine. The data from the Cybex machine and EMG will be saved onto a computer file using subject identifiers.

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 four investigators listed (Angela D'Souza, Samantha Jamosmos, Angela Nuccio, and Cynthia Villalobos) the advisor (Courtney Jensen) and Certified Kinesio Taping Practitioner (Cali Van Valkenburg) will have access to the gathered data. Confidentiality will be maintained during and after the study by saving the data, obtained from the Cybex machine, on a password protected computer. The four investigators, advisor, and Certified KT Practitioner will be allowed in the lab room while the study is being conducted on participants. While in use, the data from the cybex machine and the surveys will be kept locked up in Dr. Jensen's office. After the results of the study are presented, all files on the computer will be deleted off of the computer and the surveys will be shredded. Confidentiality will be maintained in the reporting of results by using assigned subject identifiers. Only Dr. Jensen will retain the signed consent forms in his office, which will be shredded three years after the study. Dr. Jensen will retain the subject names with the confidential identifiers. Dr. Jensen will keep the data as a password protected file on his school computer.

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.

The data will be presented at an undergraduate research conference. Once used, the surveys will be shredded, and the files from the Cybex machine will be deleted off of the password protected device. At the completion of the study, by March of 2017, all information will be deleted from the data collection computers. The original data files will be retained for three years after presentation at the research conference. The surveys obtained will be locked up in Dr. Jensen's office, and will be destroyed three years following the presentation of the data. Additionally, the data will be presented in aggregate.

VIII. Benefits, Risks, Costs

A.) What are the potential benefits to humanity?

A potential benefit to humanity is having more evidence on whether Kinesio Tape increases force output or not. Since we are comparing the type of application of the tape (inhibition versus facilitation) as well as no tape, the results will help individuals decide whether or not they want to use tape in the future.

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

The potential benefits to the subjects are knowledge of whether Kinesio Tape is beneficial or not and whether the subjects should invest in the tape or look for other options.

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

No compensation will be given.

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.**

Physically, subjects will be expected to exert themselves throughout the Cybex test. Each test will last for roughly three minutes. There is a possible risk of an allergic reaction, skin abrasion or skin irritation to the tape.
Psychologically, subjects may experience anxiety during the data collection.
Sociologically, subjects will have to share his or her weight with the researchers, advisor and CKTP. Subjects will also have to expose their upper right leg for the Kinesio Tape placement.
Additionally, there is always a loss of confidentiality risk when conducting research. There is a possibility that the subject's consent form, survey or data collected from the Cybex could be exposed to someone outside of the research team.

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

Interviewers will ask each subject to physically exert themselves as much as they can. Subjects will not be encouraged to continue if he or she is experiencing pain throughout the test. Since the movement performed in the test is concentric, the subject will likely not experience any type of stresses that produce delayed onset muscle soreness. The concentric motion will mimic everyday stresses of a recreationally active individual. To minimize the risk of an allergic reaction to the tape, participants will be asked in the survey whether or not they are allergic to Kinesio Tape, specifically adhesives. The possibility of skin abrasion or irritation is minimal, because the skin will be prepared and applied correctly by the CKTP.

If a participant expresses any type of adverse emotional behaviors, the interviewers will ask the subject if he or she would like to discontinue. The research team will use words of encouragement throughout the test to ease any emotional discomfort of the participant. While the data are displayed during the test, only the subject and one researcher will be able to see the screen. When obtaining the subjects weight, one researcher will ask the subject in private. When exposing the subject's upper leg for tape application the subject will be given three choices: to have the tape applied in the lab room without any draping, to have the tape applied in the lab room with draping, or to have the tape applied in a private room with only the CKTP.

The safeguards in place for the loss of confidentiality risk include: keeping the signed consent forms and surveys locked up in Dr. Jensen's office on the University of the Pacific campus in Main Gym, and also keeping the data collected from the Cybex machine on Dr. Jensen's password protected computer. Immediately following the collection of the consent forms and surveys, they will be placed in his office.

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

One cost is a loss of time. It will take about 5-10 minutes to complete the survey. For the physical trials, subjects will be asked to commit fifteen minutes on the three separate occasions.

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.

N/A

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 study will be explained by having the subjects read the informed consent form, presented in person and paper format at the university gym, which will explain what the study entails, the time commitment and the minimal risks of the study. A personal copy will be given to the subject and one will be kept for the researcher's records. The informed consent form will only be presented once at the gym. One of the investigators on this proposal will explain the entire data collection paradigm to the subject and ask if they have any questions.

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).

N/A

Methodology

The researchers will select a subject group consisting of 12 males and 12 females aged 18-24 from the University of the Pacific in Stockton, a northern California university. The researchers will be approaching potential participants while standing at the front entrance of the university gym, asking if they are interested in participating in our research on Kinesio Tape. If interested, they will first fill out a paper consent form and then a paper survey in person, completing the survey will take roughly five to ten minutes. The purpose of this survey is to identify recreationally active young adults who do not have injuries that could affect their performance on the Cybex Humac Norm dynamometer system. The potential subject will complete the survey at the tables near the front entrance in a public setting. However, if the participant wishes to fill the survey out in private, they will be allowed to take the survey home and return it to us in person by contacting us via email or telephone. After approximately 55 surveys are filled out, the researchers will examine each survey and see who is qualified. If the requirements are met, participants will be selected at random from completed surveys. The researchers will be responsible for collecting the data and ensuring the participants' identities are kept confidential. Subjects will be instructed to avoid intense physical activity of their lower extremities 48 hours prior to collecting data. A Cybex Humac Norm dynamometer system will be used to compare the force output of the dominant leg in three different conditions: 1) A KT application that purportedly inhibits muscle recruitment, 2) a KT application that purportedly facilitates muscle recruitment, and 3) no KT. The researchers will ensure that the taping procedures are similar by using a certified kinesio taping practitioner (CKTP). Two surface EMG electrodes will be placed on the subject's skin, over the rectus femoris muscle, to record the electrical activity produced under the three conditions. These three trials will be conducted on the same day and on three separate occasions (totalling 9 tests per subject). The order of these trials will be assigned

randomly. This study will be quantitative; the researchers will conduct a statistical analysis of the data.

Questionnaire – Kinesio Tape: Effect on Force Output

Name (First & Last):

Contact Information:

Email:

Telephone Number:

Age:

Sex:

1. Have you had a musculoskeletal injury?

If yes:

What part of the body was injured?

When was this injury?

Has your injury completely healed?

2. Have you ever used Kinesio Tape?

3. Are you allergic to Kinesio Tape (including elastin)?

4. Would you be opposed to shaving a section of your upper leg (if needed)?

5. How many days per week on average do you exercise? On average, how long do you exercise each day?

INFORMED CONSENT

Kinesio Tape: Effect on Force Output

You are invited to participate in a research study which will involve multiple tests on a Cybex Humac Norm dynamometer system. The force output of your dominant leg will be measured with and without Kinesio Tape. Our names are Angela D'Souza, Samantha Jamosmos, Angela Nuccio, and Cynthia Villalobos, and we are undergraduate students at the University of the Pacific, Health, Exercise, and Sport Sciences. You were selected as a possible participant in this study because of your age, gender, presence of a recreationally active lifestyle (defined as participating in at least 30 minutes of moderate intensity, physical activity on at least 3 days of the week for at least 3 months), and lack of injury in the lower body (e.g. legs, knees, ankles, feet).

The purpose of this research is to identify the effectiveness of Kinesio Tape on force output. If you decide to participate, you will first complete a survey which will take roughly five to ten minutes to complete. If you meet the requirements, you will then be taped by a certified kinesio taping practitioner on your dominant upper leg before being measured on the Cybex Humac Norm dynamometer system. You may be asked to shave a portion of your thigh. Your participation in this study will last roughly fifteen minutes for three separate occasions. Therefore, the total time commitment is roughly forty-five minutes.

There are some possible risks involved for participants. These include physically exerting yourself throughout the Cybex test, developing adverse emotional behaviors to the testing (e.g. anxiety), and possible discomfort from disclosing your weight and exposing your dominate upper leg. Additionally, there is always a loss of confidentiality risk when conducting research. There is a possibility that the subject's consent form, survey or data collected from the Cybex could be exposed to someone outside of the research team. There are some benefits to this research, particularly that active individuals will be able to identify the effectiveness of Kinesio Tape and decide to invest in the product or look toward other products.

If you have any questions about the research at any time, please call researcher Cynthia Villalobos at (209) 351-1808, or advisor Dr. Courtney Jensen at (209) 946-3133. 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) 946-7716. In the event of a research-

related injury, please contact your regular medical provider and bill through your normal insurance carrier, then contact the Office of Research & Graduate Studies.

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 ensure your confidentiality include: Surveys viewed only by the research team, shredding of surveys after the study, and a password protected device for data collection on the Cybex machine. The data obtained will be maintained in a safe, locked location and will be destroyed three years following the presentation of the data at a research conference.

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.

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

Signature _____ Date _____