MONTANA STATE UNIVERSITY BILLINGS
Access & Excellence

Office of Research Compliance
Fall 2016/Spring 2017

APPLICATION FOR HUMAN SUBJECTS RESEARCH APPROVAL

MSUB requires all projects that involve human subjects undergo review by the Institutional Review Board (IRB). Approvals are valid for 12 months and may be eligible for a 6-month renewal. For more information regarding human subject research, see http://www.msubillings.edu/orc/pdf/IRB_Guide.pdf.

Make sure you have the current application form. Old forms will **not** be accepted.

1. Date: April 26, 2017

2. Project Title: Retrospective Study on External Lower Limb Support and the Incidence and Severity of Knee Injuries

3. Principal Investigator

Name [redacted]

Email [redacted]

Address [redacted]

Phone [redacted]

Relationship to MSUB: ☐Faculty ☐Staff ☒Graduate Student ☐Undergraduate Student
☐No Affiliation, explain:

College/Department: Health & Human Performance

4. Faculty Sponsor - required for student projects.

Name [redacted]

Email [redacted]

College/Department: Department of Health and Human Performance

5. Co-Principal Investigators

1. Name
   Email
2. Name
   Email
3. Name
   Email

6. Application Type: ☒New ☐Renewal
☐Modification/Addendum, explain:
☐Change of Status, explain:

7. Project Type: ☐Faculty Research ☒Thesis/Capstone
☐Class Project, name:

☐Other, explain:

8. Funding Source: N/A

9. Collaborative Effort - Are any other institutions involved the in the proposed project? ☒No ☐Yes

- If yes, give name and nature of the collaborative relationship:

10. Other Approval - Has another IRB approved the research study? ☒No ☐Yes

- If yes, explain and include a copy of the approval form:

11. Project Description - Provide a concise but thorough description of the steps to be undertaken in the proposed activity and address the involvement of human participants: Following notification by the certified athletic trainer (ATC) of knee injuries sustained by varsity athletes at the two participating institutions, I will contact them to obtain informed consent and have them complete the inclusion questionnaire. Following this, the type of external lower limb support and severity and type of knee injury will be determined through communication with the athlete, ATC, and the use of injury notes from sportsware (injury tracking software). The type and severity of injury as well as type and location of external support will be coded and entered into SPSS. Data from all participants will be analyzed to determine correlation between the different types of external support and the incidence rates and severity of knee injuries.

12. Objective - Briefly state what you hope to find or observe in this study: In this study, I expect to find an increased incidence of knee injuries in the externally supported group. This is due to the increase of force transfer through the knee joint when structures of the ankle are supported in such a way as to decrease the amount of force applied to them during physical activity.

13. Procedures

Location(s) of study: Montana State University-Billings and Rocky Mountain College

Do you have approval to be in this location? ☐No ☒Yes

- If yes, attach a letter from a representative of the location (on letterhead), authorizing you to utilize the space

Variables to be studied or questions to be addressed: DV: knee injuries; IV: type and location of external lower limb support (tape or brace; ankle, Achilles tendon, medial longitudinal arch, and toes)

Data Collection Methods; include sample data collection instrument: Inclusion questionnaire to confirm participants are eligible and meet the specified criteria and Sportsware to look up specific injury data.

If a debriefing is planned, describe the procedures and include a sample of the debriefing form or script: N/A

14. Project Information - Mark if the project involves any of the following:

a) Deception of participants ☐
b) Withholding information from potential participants ☐
c) Any form of punishment ☐
d) Questions about any kind of illegal or illicit activity ☐
e) Purposeful creation of anxiety ☐
f) Any procedures that might be viewed as an invasion of privacy ☐
g) Physical exercise or stress ☐

h) Administration of any substance (e.g., food, drugs) ☐
i) Procedures that might place subjects at risk ☐
j) Any forms of potential abuse ☐
k) Exposure to materials that might be considered offensive ☐
l) Inducements for participation (including course credit) ☐

For each item marked above, please explain:

15. Participants – Mark if the project targets participants from any of the following groups:

m) Individuals under the age of 18 ☐
n) Individuals over the age of 65 ☐
o) Individuals who are educationally or economically disadvantaged ☐
p) Individuals who are unable to provide their own legal informed consent ☐
q) Individuals who are in institutions, e.g., prisons, nursing homes ☐
r) Individuals who have physical or mental disabilities ☐

Mark if the project incidentally includes participants from any of the following groups:

s) Individuals under the age of 18 (if yes, explain below methods for reasonably excluding minors) ☐
t) Individuals over the age of 65 (if yes, explain below whether or not participation represents any specific risk to seniors) ☐
u) Individuals who are educationally or economically disadvantaged (if yes, explain below whether or not participation represents any specific risk to persons with any of these disadvantages) ☐
v) Individuals who are unable to provide their own legal informed consent (if yes, explain below whether or not participation represents any specific risk to persons with this disadvantage) ☐
w) Individuals who are in institutions, e.g., prisons, nursing homes (if yes, explain below whether or not participation represents any specific risk to persons in any of these contexts) ☐
x) Individuals who have physical or mental disabilities (if yes, explain below whether or not participation represents any specific risk to persons with any of these disadvantages) ☐

For each item marked above, please explain:

16. Source of participants

Will sample be random? ☒No ☐Yes

- If no, please describe the criteria that will be used to select participants: Participants will be selected based on the assessment and/or treatment of their acute knee injuries in the institutions' athletic training rooms.

Number of participants: 50

Justification of sample size: Based on the number of knee injuries sustained by athletes at the two participating institutions in the previous academic year, it is appropriate to estimate that 50-70 athletes will experience knee injuries at some point during the academic year.

Characteristics of participants other than those above: Participants will be any athlete at the two participating institutions who sustains an acute knee injury while taking part in their sport or any type of team sanctioned training.

Recruitment procedures to be used: All athletes who are diagnosed by an ATC as having an acute knee injury directly caused by their sport participation will be contacted to determine interest in participating in the study. Those who agree will be provided with an informed consent form as well as the inclusion questionnaire.

17. Risks, Protection, and Benefits

Identify any foreseeable physical, psychological, social, or legal risks for participants: There are no forseeable risks associated with the study as it is a retrospective study that considers already sustained injuries and does not interfere in any way with the patient's treatment.

Describe the measures that will be taken to minimize the risks or to protect participants from potential risks: There are no forseeable risks associated with this study.

Describe any reasonably expected benefits for research participants: Participants will not receive immediate benefits as a result of participating in this study, however, the results may be beneficial for athletes when determining if they should utilize external lower limb support and if so, which type they should use.

18. Confidentiality and Anonymity

Is the study: ☐Confidential ***or*** ☒Anonymous

Explain the procedures that will protect the confidentiality or anonymity of the research participants: Participants will be categorized based on the severity and type of injury they sustain. This will be recorded as a number and no identifying features of the athlete will be used in the processing of data. Participants' data will be anonymous after collection and processing.

With regard to individuals' privacy concerns and identity issues, explain how information will be gathered, maintained, stored, and ultimately destroyed or archived: Information will be gathered from participants by a questionnaire completed by them as well as through their injury data records in the Sportsware program. Participants will then be categorized based on their injuries and external limb support and their data will be entered into a spreadsheet. Once all data has been transferred from the paper questionnaires to the spreadsheet, questionnaires will be shredded. All spreadsheets and SPSS data sets will be kept on a flash drive that is stored in a secure location.

Will information relevant to their participation be provided to subjects after the project? ☒No ☐Yes

- If yes, explain the contexts and nature of anticipated future contacts:

19. Informed Consent

Will a written consent form be used? ☐No ☒Yes

- If yes, attach sample of informed consent and describe the procedures by which informed consent will be obtained: When athletes report to the athletic training room with an acute knee injury, they will be provided with an informed cosent to then be returned to the athletic training room once completed.
- If no, answer the following questions to the best of your ability:

Will a waiver of consent be gathered? ☐No ☐Yes

- If no, explain why it would be an impractical step in the process of gathering data:
- If yes, explain waiver documentation procedures and attach any necessary accompanying information:
- Is it foreseeable that the rights or welfare of any subjects are likely to be adversely affected by waiving informed consent? ☐No ☐Yes
  - If yes, explain the nature of the adversity and the steps to be taken to minimize the effects:

20. Conflict of Interest

This project is: ☐Clinical Trial Research ☒Non-Clinical Trial Research

☐Other

By signing below, I hereby certify:

1. I have read and understand Montana State University Billings' Conflict of Interest Policy http://msubillings.edu/humres/procedures/408%20-%20Conflict%20of%20Interest.pdf
   ☒ PI ☐ Co-PI ☐ Co-PI ☐ Co-PI
2. I have (check only **ONE BOX** per contributing investigator):
   a) No relationships, contractual commitments, or financial interests that are or might reasonably be perceived to be in conflict with my duties and responsibilities at MSU Billings;
   ☒ PI ☐ Co-PI ☐ Co-PI ☐ Co-PI
   b) A potential conflict of interest which has been duly disclosed previously and there has been no change which requires an updated disclosure; or
   ☐ PI ☐ Co-PI ☐ Co-PI ☐ Co-PI
   c) Potential conflicts of interest not previously disclosed. If checked, you must complete and submit a Conflict of Interest Disclosure Statement http://www.msubillings.edu/humres/forms/Conflict%20of%20Interest%20Form.pdf to the Human Resources Office and provide a copy to the ORC
   ☐ PI ☐ Co-PI ☐ Co-PI ☐ Co-PI

By signing and submitting this form, you agree that the information you have provided is true and accurate to the best of your knowledge and ability and acknowledge your continuing obligation to update disclosures when there is a significant change in personal or financial interests creating potential Conflicts of Interest.

Students must submit a hardcopy with a penned signature. Faculty and staff may sign and submit electronically.

[redacted]

Co-Principal Investigator Date

Co-Principal Investigator Date

Co-Principal Inv[redacted]

Faculty Sponso[redacted]

To expedite review by the IRB, make sure you answered each question completely, acquired all necessary signatures, and have included all corresponding documents. Failure to do so will delay the IRB's ability to grant approval; expect decision notification within 10 working days.

Office of Research Compliance
203 McMullen Hall
Montana State University Billings
1500 University Drive
Billings, MT 59101
grants@msubillings.edu
406-657-2046

Inclusion Questionnaire

(a) Have you previously experienced one or more knee injuries to the same extremity as your current injury?

(b) If yes, did you undergo surgery on that knee?

(c) If yes, have you completed a full course of rehabilitation under the supervision of an ATC, PT, or MD and been cleared to return to full participation?

(d) If you did not undergo surgery, did you complete a full course of rehabilitation under the supervision of an ATC, PT, or MD and been cleared to return to full participation?

(e) If you were not cleared to return to full participation, why not?

(f) If you were not cleared to return to full participation, what are your restrictions?

ROCKY MOUNTAIN COLLEGE

Department of Athletics

To the IRB Approval Committee;

This letter serves as the official notice that MSUB graduate student [redacted] has been approved to carry out research pertaining to her thesis at Rocky Mountain College. Data will be collected from varsity athletes from all sports teams who have sustained sport related knee injuries.

All data will be collected from current Rocky Mountain College athletes on campus at [redacted]

[redacted]

[redacted]

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All data will be collected from current MSUB athletes on campus at [redacted]

[redacted]

[redacted]

Consent Form

Title of Study:
Retrospective Study on External Lower Limb Support and the Incidence and Severity of Knee Injuries

Description:
Signing this form indicates that you voluntarily agree to participate in a research study entitled: Retrospective Study on External Lower Limb Support and the Incidence and Severity of Knee Injuries to be carried out by [redacted] under the supervision of [redacted]
Your role as a participant in this study would require you to complete an inclusion questionnaire regarding previous injuries and any rehabilitation you have undergone as a result of those injuries. It is possible that the researcher may contact you for information related to your injury that is not available in your treatment file.

Disclosure of Risks and Discomfort:
There are no foreseeable risks or costs to the participant associated with this research.

Potential Benefits:
There will be no immediate benefit to participation in this research. The results of this research will be beneficial to the sports medicine community and any athletes who utilize lower limb support or are considering it.

Protection of Confidentiality:
To ensure confidentiality, all injury data will be coded before being catalogued and inputted for data analysis. Once all pertinent participant information has been transferred to spreadsheets and coded the inclusion questionnaire will be shredded.

Voluntary Nature of Participation:
Your participation in this study is completely voluntary and you may choose to withdraw at any time by contacting either of the individuals listed above. At no point will participants be coerced or bribed to participate in this research. Withdrawal from this study will not affect the athletic training services available to you as an athlete or have any other consequences.

Contact information:
Any questions or concerns regarding this study can be directed to [redacted] or [redacted]
Any questions regarding your rights as a participant can be directed to the MSU Billings Institutional Review Board at [redacted] which has approved this study.

Consent:
I have read this consent form and have been given the opportunity to ask questions. I give my consent to participate in this study.

Participant's Signature _____ Date _____
Investigator _____ Date _____