R·I·T

Rochester Institute of Technology
INSTITUTIONAL REVIEW BOARD
585-475-7673 ~ www.research.rit.edu/hsro ~ hsro@rit.edu

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Signed original received: _____
HSRO #: _____

FORM A: Request for IRB Review of Research Involving Human Subjects

- **To be completed by the investigator** after reading the RIT Policy for the Protection of Human Subjects in Research, found in the *Institute Policies and Procedures Manual*, Section C5.0, and on the Office of Human Subjects Research website, http://www.rit.edu/research/hsro/process_geninfo.php.
- Submit **BOTH** an **electronic version to** hsro@rit.edu **AND a signed hard copy of the completed Form A AND ALL attachments (consents, instruments, tasks, etc.)** to **HSRO**, University Services Center, Suite #2400

Project Modeling Trunk Energy Flow in Collegiate Baseball Pitchers Using a Damped Torsion Spring Oscillator and its Relationship to Fatigue and Competitive Performance		
SRS Proposal # (Required if associated with a sponsored project, # assigned by SRS and available in RAPID:		
Investigator's Name: Charles Arnold	Investigator's Phone: 951-870-1727	Investigator's Email: Cja4221@rit.edu
Investigator's College and Department: College of Science and Physics/ College of Health Science and Technology and Exercise Science		
Project Start Date: 9-26-22	Date of IRB Request: 8-26-22	Data Collection Start Date: 9-26-22
If Student, Name of Faculty Supervisor: William Brewer	Faculty's Phone: 585-370-1716	Faculty's Email: wsbscl@rit.edu
If Not Employed or a Student at RIT, List Name, College & Dept. of RIT Collaborator:	RIT Collaborator's Phone:	RIT Collaborator's Email:

Will this project be funded externally? ☐ Yes ☒ No	Is the Investigator a student? ☒ Yes ☐ No		
If yes, name of funding agency and proposal #:			
Status of project:	☒ Submitted on 9-26-22	☐ Funding pending	☐ Funding confirmed
Do you have a personal financial relationship with the sponsor? ☐ Yes ☒ No If yes, please read RIT policy C4.0 – Conflict of Interest Policy Pertaining to Externally Funded Projects. Complete the **Investigator's Financial Disclosure Form** and attach it to this Form A. *All information will be kept confidential.*			

BY MY SIGNATURE BELOW, I ATTEST TO AN UNDERSTANDING OF AND AGREE TO FOLLOW ALL APPLICABLE RIT, SPONSOR, NEW YORK STATE, AND FEDERAL POLICIES AND LAWS RELATED TO CONDUCTING RESEARCH WITH HUMAN SUBJECTS. If significant changes in investigative procedures are needed during the course of this project, I agree to seek approval from the IRB prior to their implementation. I further agree to immediately report to the IRB any adverse incidents with respect to human subjects that occur in connection with this project.

Signature of Investigator Date

Signature of Faculty Advisor (for Student) or RIT Collaborator (for External Investigator) Date

Signature of Department Chair or Supervisor Date

Complete the attached Research Protocol Outline and attach to this cover form with other required attachments.

Attachments required for all projects:

- ☒ Project Abstract
- ☒ Human Subjects Research (HSR) Completion Report. Create an account at (https://www.citiprogram.org/) Training information at http://www.rit.edu/research/hsro/training

Attachments required where applicable:

- ☒ Informed Consent Materials
- ☐ Questionnaire or survey
- ☐ Relevant Grant Application(s)
- ☒ Letter of Support from School Principal
- ☐ Cover letter to subjects and/or parents or guardians
- ☐ External site IRB approval
- ☐ Other: General Protocol

Form A (continued): Research Protocol Outline

- The RIT Institutional Review Board (IRB) categorizes Human Subjects Research into three Risk Types (Exempt, No Greater than Minimal Risk, and Greater than Minimal Risk, defined at the end of this form). The IRB makes the final determination of risk type.
- **Please complete this entire form (1 through 10 below). ENTER A RESPONSE FOR EVERY QUESTION.** If a question does not apply to your project, please enter "N/A". Leaving questions blank may result in the form being returned to you for completion before it is reviewed by the IRB.
- Underlined terms are defined at the end of this form.

FOR ALL PROJECTS, please complete 1-10 below.

1) If you believe your project qualifies for Exemption, which exemption number(s) apply?
(Note: The IRB makes the final determination of Exemption)

Exception 2. There are no direct interventions involved administrated by any of the investigators. This study is strictly an observational study of examining the biomechanics of the torso to look at trunk energetics in pitching session and competitive pitching session.

2) Describe the research problem(s) your project addresses.

Many players do not understand how to utilize the transfer of energy of the kinetic chain. When most players throw, somewhere along the chain, there is a leak of energy. These leaks have an effect on the athlete. Effects can vary from lower ball kinematics to more stress and torques on joint segments of the body. When players want to throw hard, they will think to move their arm faster which can put more stress on the arm and shoulder. Recent data has shown an increase of 50% in the number of UCL (elbow) reconstructions performed on high school–aged and younger athletes.

3) Describe expected benefits to subjects and/or knowledge to be gained from your project.

To increase energy transfer efficiency and decrease arm stress, this experiment will construct a model in which the athletes' trunk will act as a spring that experiences a torsion force. In order to model the energy flow between maximum pelvis velocity, and maximum torso velocity, a 4D Motion Sensors and ProplayAi markerless capture will be utilized. This investigation will help players find a more constructive and safe way to increase performance while also decreasing elbow and shoulder kinetics, which can be extremely harmful to the body if not well managed.

4) Describe the population sample for your project.

a) How many subjects will participate in this project?
12 subjects

b) How will these subjects be identified and selected for participation?
Participants will be selected from both the MCC and RIT Baseball team pitching staff.

c) Describe the rationale for inclusion or exclusion of any subpopulation.

Members of the MCC and RIT baseball team who have been medically screened by their Team Physician and complete a verbal pain evaluation before participation will be admitted as a participant.

Athletes who do not pass the Team Physician administered physical will be excluded as a participant.

Athletes who do not pass Verbal Pain Evaluation will be excluded as a participant.

d) How will you recruit subjects?
Email

e) Describe any incentives for participation you plan to use.
None

5) Will you include any of the following vulnerable populations in your research? (Check any that apply)

☐ Children, Fetuses or Neonates
☐ Individuals with Intellectual Disabilities, Cognitive Impairment, or Psychiatric Illness
☐ Pregnant Women ☐ Prisoners or Parolees ☒ Students or Employees

If any of these populations are to be included, please addresses the following:

a) Rationale for selecting or excluding a specific population:
Membership of the MCC and RIT Baseball Team in the FALL

b) Description of the expertise of project personnel for dealing with vulnerable populations:
Principal Investigator has 16 years of experience within baseball.

c) Description of the suitability of the facilities for the special needs of subjects:
Data will be collected in the designated RIT facilities for participation in baseball and MCC baseball facilities.

d) Inclusion of sufficient numbers of subjects to generate meaningful data:
As a result of completing the study protocol, sufficient data will be generated.

6) Describe the data collection process.

a) Will the data collected from human subjects be <u>anonymous</u>? ☐ Yes ☒ No

b) Will the data collected from human subjects be kept <u>confidential</u>? ☒ Yes ☐ No

c) Describe your procedures for ensuring anonymity and/or confidentiality:
Data will be encrypted using password protected drives. Only investigators will be handling data and subjects will be assigned identification numbers to protect name confidentiality.

d) How much time is required of each subject?

Two 30min sessions

e) If subjects are students, will their participation involve class time?
No

f) What methods, instruments, techniques, and/or other <u>sources of material</u> will you use to gather data from human subjects?

The RIT Baseball Biomechanics Lab will use wearable sensors operating at 200Hz to collect motion capture data. A PitchLogic will be used to record ball velocity and spin rate.

ProplayAi will also be used to collect motion capture data.

Full body kinematics and kinetics will be calculated with ProplayAi and Wearable accelerometer Analysis using the created model.

Outcome measures include questionnaire responses, height, weight, hand size, thorax and pelvis circumference, ball velocities and spin, heart rate, and full body kinematics and kinetics.

7) Will this research be conducted at another university or site other than RIT? ☐ Yes ☒ No
If yes, describe location: N/A

Note: If you will be conducting human subjects research at another university or college, you will also need to obtain IRB approval from that institution. **Attach a copy of that approval to this application.**

8) Describe potential <u>risks</u> (beyond <u>minimal risk</u>) to subjects:

a) Are the risks physical, psychological, social, legal, or other?
No

b) Assess their likelihood and seriousness to subjects:

None

c) Discuss the potential benefits of the research to the population from which your subjects are drawn:

Participants are going to decrease shoulder forces and elbow torques to reduced likelihood of being injured. Participants will be protecting their joint segments and the longevity of their throwing careers.

d) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others, or in relation to the importance of the knowledge to be gained as a result of the proposed research:

All activities will be analyzed, and players will be given feedback to improve their mechanics. Players are not being asked to do anything more than they already do in a practice setting.

e) Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness:

Activities will be approved by advisors and their schools Pitching Coach. All experts will be involved with data collection and an investigator will always be on site to ensure player protection.

f) Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects:

All activities will be supervised by primary investigator. Players will have access to training facilities as well as recovery facilities to facilitate training methods. The RIT Pitching Coach has 8 years of experience coaching pitchers.

9) Will you be seeking informed consent? ☒ Yes ☐ No

If yes, describe:

a) What information will be provided to prospective subjects?

Goal of the project, background of theory, model being used to analysis biomechanical data, materials used to record data, names of investigators and contact info, protection of research sharing information, who can participate and requirements to participate, process of discontinuation of participation.

b) What (if any) information will be concealed prior to participation, and why?

none

c) How will you ensure consent is obtained without real or implied coercion?

Subjects will be told that participating is optional. Each participant will sign their name to confirm consent.

d) How will you obtain and document consent?

Printed inform consent forms will be signed in person before participation.

e) Who will be obtaining consent? Provide names of specific individuals, where available, and detail the nature of their preparation and instructions for obtaining consent.

Charles Arnold, and William Brewer. Charles is the principal investigator that will attain consent through email and players will either email form completed back to principal investigator or print and deliver to investigator.

William Brewer is the Co-Investigator that will obtain consent and assent in the same manner

10) Attach a copy of all additional materials (Consents, protocol, scripts, instruments, tasks, etc.- everything a subject does or sees) to this application.

RIT IRB Risk Type Classification

EXPEDITED

Human Subjects Research – Definitions

For definitions please see the "2018 Requirements" of Human Subjects Regulations at 45Part46.102
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html