Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Vulnerable Participants

(45 CFR 46.201-207; 46.301-306; 46.401-409)

Maricia Dilan, IRB Professional

mdilan@uga.edu

Vulnerable Participants

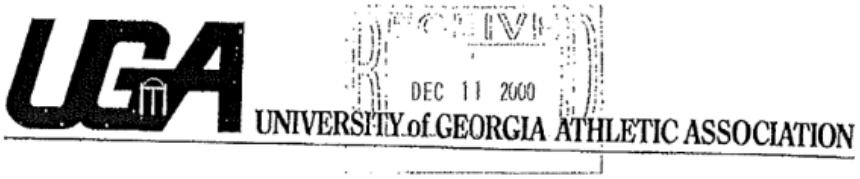
Additional Protections to:

- **Subpart B** (CFR 46.201-207) – Pregnant Woman, Human Fetuses and Neonates
- **Subpart C** (CFR 46.301-306) – Prisoners
- **Subpart D** (CFR 46.401-409) – Children

Other Vulnerable Participants

- Students
- Employees
- Economically/educationally disadvantaged
- A specific group based on religion, race, ethnicity, immigration status, language, or sexual orientation
- Physically Disabled
- Terminally Ill
- Mentally-disabled/ cognitively-impaired/ severe psychological disorders
- **OTHERS** (e.g., **Athletes**)

Protocol for Research Studies Involving Student-Athletes



Protocol for Research Studies Involving Student-Athletes

1. Proposal for research study should be forwarded to the director of sports medicine, who will distribute copies to the director of athletics, team physicians, head coach of sport to be involved, and any other pertinent individuals (example: director of strength and conditioning with any research project involving strength and conditioning). The proposal should include specific information regarding purpose of study, benefits, risks, nature of activity and dates to be performed, safety issues, individuals responsible for and performing study, etc. The proposal will be reviewed by the above individuals and either approved, rejected or modifications suggested to study.
2. If approved by the athletic association, a copy of the IRB approval form should be forwarded to the director of sports medicine.
3. Upon receipt of the IRB approval form and final approval by the athletic association, the researcher will be provided with a written letter formally authorizing the study. No study may begin without written approval.
4. With any study conducted that does not necessarily involving the athletic association but may involve student-athletes being recruited and involved as subjects, researchers should instruct the student-athlete prior to participating that they may not participate without express written consent of their sport coach. This is to assure that at all times, the sport coach is aware of the student-athlete's participation and approves such participation. We are aware that many student have the opportunity to participate in research studies throughout the year; however, the researcher may not be aware of factors influencing participation in the study, such as practice and competition schedules, injuries, etc.

Due to risk management issues and legal liability concerns, no research projects can be allowed to utilize athletic facilities and/or equipment with non-athletes.

Protocol for Research Studies Involving Student-Athletes (cont.)

1. Proposal for research study should be forwarded to the director of sports medicine, who will distribute copies to the
    a. director of athletics,
    b. team physicians,
    c. head coach of sport to be involved,
    d. and any other pertinent individuals (e.g., director of strength and conditioning with any research project involving strength and conditioning).

The proposal should include specific information regarding

- purpose of the study, benefits, risks,
- nature of activity and dates to be performed,
- safety issues, individuals responsible for and in performing study, etc.

The proposal will be reviewed by the above individuals and either approved, rejected, or modifications suggested to study.

Protocol for Research Studies Involving Student-Athletes (cont.)

2. If approved by the athletic association, a copy of the IRB approval form should be forwarded to the director of the sports medicine.

3. Upon receipt of the IRB Approval form and final approval by athletic association, the researcher will be provided with a written letter formally authorizing the study. No study may begin without written approval.

Protocol for Research Studies Involving Student-Athletes (cont.)

4. For any study conducted that does not necessarily involve the athletic association but may involve student-athletes being recruited and involved as subjects, researchers should instruct the student-athlete prior to participating that they may not participate without express written consent of their sport coach. This is to ensure that at all times, the sport coach is aware of student-athlete's participation and approved such participation. We are aware that many student have the opportunity to participate in research studies throughout the year; however, the researcher may not be aware of factors influencing participation in the study, such as practice and competition schedules, injuries, etc.

Due to risk management issues and legal liability concerns, no research projects can be allowed to utilize athletic facilities and/or equipment with non-athletes.

Vulnerability: Dynamic Lens

- **Inherent** – Intrinsic to human condition
  - E.g., Aging, ill-health
- **Situational** – Vulnerability caused by situation/context and not based upon membership in a protected class
  - E.g., Intermittent aid-workers in hurricane prone area vs. villagers living there
- **Pathogenic** – Created by morally dysfunctional interpersonal relationships, socio-political oppression/injustice, inequality in power
  - E.g., Elder abuse, military sexual trauma

Vulnerability: Dynamic Lens (cont.)

- The role of the IRB is to implement research that mitigates inherent vulnerability and works to eliminate/minimize pathogenic vulnerabilities.

Case Study:

- **Study Purpose:** To measure skeletal muscle mitochondrial capacity, muscle endurance and strength on individuals with prior knee reconstruction surgery
- **Target Population:** Female student-athletes, 18-25 years old, have had a knee reconstruction surgery and completed their rehabilitation program 6 months to 5 years from the testing date
- **Recruitment:** Flyers (athletic facilities); Emails (forwarded by coaches & trainers)
- **Screening:** Phone or in-person screening
- **Consent Process:** Will be obtained and documented in person at the time of testing
- **Procedures:**
  1. Medical Questionnaires – done online prior to the testing
  2. Accelerometer – muscle endurance (both hamstring & quadriceps)
  3. Near Infrared Spectroscopy (NIRS) and blood pressure cuff – mitochondrial capacity of hamstring & quadriceps
  4. Biodex machine – skeletal muscle strength of hamstring & quadriceps
  5. Ultrasound – how much skin and fat are over the muscles being tested

1. What are the vulnerabilities associated with how this case-study is designed (inherent, situational, & pathogenic)?

Inherent

- Female
- Youth
- Injuries

Situational

- Being a student-athlete

Pathogenic

- Institution specific policies on student-athletes
- Potential for undue influence or coercion

2. How can a study be implemented while mitigating the vulnerabilities?

- Making sure that the study has **Letter of Support** from the Athletic Association or a language in the recruitment materials and consent form that athletes should consult their sport coach prior to participating in the study

3. How can the IRB view the study design through vulnerability lens?

- Don’t ignore student-athletes due to busy schedules, on the other hand, do not overuse them in research

- Risk/Benefit ratio

MEMORY REVIEW

Memory Review

- In some studies, the board has discussed the length of time that must have passed since surgery for participants to be eligible for participation and if a medical clearance should be obtained for some or all (based on the time since surgery).
- **Informed Consent Document**
  - Describe mitochondrial capacity in lay terms.
  - Describe the Biodex procedure in lay terms.
  - "Testing may be uncomfortable but should not be painful."

    This may give the participant a false impression. It is important that the participant be presented with information sufficient to make a fully informed consent without bias in the language of the consent form.

Helpful Links/Resources:

- Participant Selection and Recruitment
- Research with Vulnerable Populations
- Students as Research Participants
- The Many Faces of “Coercion and “Undue Influence”

Thank you!