**UNIVERSITY OF NORTHERN IOWA**

**HUMAN PARTICIPANTS REVIEW INFORMED CONSENT**

*Template for Writing a Consent Text for Studies Involving Exercise*

*Remove all instructions before uploading your file.*

**RESEARCH STUDY TITLE**:  *(Enter title as it appears on the IRB application)*

**PRINCIPAL INVESTIGATOR(S)**

This study is being conducted by…

You must list the name of the Principal Investigator, Co-PI’s, Faculty Advisor (if applicable), University affiliation, and department. If this study is being conducted collaboratively with another institution, you must also state that here.

**INVITATION TO PARTICIPATE**

You are being asked to participate in a research study.The following information is provided to help you make an informed decision about whether or not to participate. This is completely voluntary. Please read this form and ask any questions you have before agreeing to be a part of this study.

**PURPOSE OF STUDY**

The purpose of this study is to …

[State clearly and accurately what the study is designed to discover or establish. Typically, one or two concise sentences is sufficient]. It is funded by [Insert Sponsor or funding agency name, if any].

**EXPLANATION OF PROCEDURES**

If you agree to be in the study, you will be asked to do the following things:

 [Insert explanation of all activities/tests that are included in the study (e.g., assignment to study groups, study visits, surveys and questionnaires, focus groups, audio or video recordings, etc.). Include the following:

* Where the activities are performed and how frequently they are performed
* State if audio or video recordings will be used
* If interviews are conducted, explain if they are in person, in groups or over Zoom
* The expected amount of time each activity and/or visit will last
* The length or duration of subject participation
* Which activities are experimental and which would be done even if the subject does not participate in the research
* Explain what will happen to the data/information at the end of the study.
* If the study involves a survey or questionnaire, include a statement that the participant is free to skip any question they prefer not to answer
* If the study includes activities that are part of the participant’s normal or required training, be clear about which activities are normal and required training and which ones are solely research activities: For example, “*If you decide to participate in this study, your data from the Pre-season Movement Efficiency Screens will be used for research purposes. The screen is a part of your normal pre-season physical that all athletes will complete, regardless of participation in this study.”*

The researchers have the training and experience to direct the study’s procedure.

[Provide information on training, certifications, and/or experience of the person who will be performing the testing or training, including CPR/First Aid.]

**DISCOMFORTS, RISKS AND COST**

While participating in the study, the potential risks are…

[Describe any physical, psychological, social, legal, and/or economic risk(s) or cost(s) resulting from the project. If injuries may arise, note who will be responsible for any medical costs. Only discuss those risks that may arise from research activities, or from sharing one’s data generated from associated program activities (e.g., confidentiality risks). Also, discuss how you will mitigate or reduce these risks. If there are no more than minimal risks--discomfort, time, or inconvenience--this must be stated].

Sample language for specific potential risks, when applicable:

1. Sub-maximal or Maximal Aerobic Testing & Muscular Strength/Endurance/Power

“With any exercise, there is the possibility that abnormal responses could occur. These include unexpected changes in blood pressure, irregular heart rate, fainting, shortness of breath, fatigue, muscle cramps, muscle soreness or joint injury, and in rare cases, a cardiac event. Risks will be minimized by researchers evaluating and implementing a standardized exercise protocol (warm-up and cool down), and having an emergency plan in place to follow if needed.”

1. Body Composition
2. Underwater Weighing: “There is a possibility of falling while entering or leaving the underwater weighing tank, and a possibility of becoming anxious when exhaling with your head under water.”
3. Bioelectrical Impedance: “There is a possibility of irregular heart rate or that an implanted electronic device may malfunction when a low voltage electrical current is passed through the body. You agree not to participate if you have an implanted electronic device (e.g., pacemaker, cochlear implant) or if you are pregnant.”
4. Skinfolds: “There may be slight discomfort as the calipers pinch the skin. This could result in redness and bruising of the skin at the skinfold site. There may also be some mild social discomfort as the researcher pinches skin at (name sites). This risk will be minimized by testing in a private area.”
5. Bod Pod: “There is a possibility some mild anxiety might develop while sitting in a small enclosed capsule.”

3. Range of Motion (Flexibility)

“With any exercise, there is the possibility for abnormal responses to occur. These include muscle soreness, and muscular strain or joint injury. An emergency plan is in place and will be followed if needed.”

4. Balance

“There is a possibility of falling which could result in injury. The risk will be minimized by researchers providing appropriate support to subjects during the balance challenge. Support will include (e.g., stable rails, a trained assistant in close proximity, physical support, and/or a belt or harness). An emergency plan is in place and will be followed if needed.”

An Emergency Action Plan has been developed for this study…

All studies involving exercise must have a written emergency plan (guidance can be found on the [IRB Forms](https://rsp.uni.edu/IRB-forms) webpage). This should be mentioned in the consent document, regardless of the type of study, and that it is available for review upon request. For studies where the exercise is part of normal or required training, it is expected that an emergency plan is already in place and will be followed, as part of the normal or required training (e.g., strength and conditioning room, athletic training). This emergency plan should be available upon request.

It is your responsibility to notify the researcher if you experience any adverse effects or any response that you find unusual or unexpected during or after exercise.

Include responsibility of the subject to notify the researcher of any adverse effects. For example: “*It is your responsibility to notify the researcher if you experience dizziness, nausea, lightheadedness, unusual pain, or any response that you find unusual or unexpected during or after exercise. You must do what you think is safe and not push yourself too far.”*

In the unlikely event that any injury or illness occurs as a result of your participation in this research, you will be responsible for the cost of medical care…”

[Include information about responsibility of medical care. If your sample involves NCAA DI athletes performing exercise outside their normal or required training, include this statement also: *“If you are a UNI student-athlete and covered under the UNI Athletic Department’s secondary health insurance, this secondary insurance cannot be used to pay for research-related injuries].*

**POTENTIAL BENEFITS**

Researchers conduct studies to answer questions and learn new information. Some research might help change or improve the way we do things in the future. You [may not / will not] benefit from being in this study but we hope to learn things that will help researchers in the future.

[Describe any direct benefit(s) that may result from the study. When stating potential benefits, focus on concrete benefits that are independent of outcomes, accruing as part of interventions and data collection procedures. If there are no direct benefits, state that there are no direct benefits. Compensation is not a benefit]

**PRIVACY AND CONFIDENTIALITY**

Information obtained during this study which could identify you will be kept confidential. The summarized findings with no identifying information may be published or presented at a scholarly conference.

**If the study is online,** state: No guarantees can be made regarding the interception of data transmitted electronically.

**If participants’ performance may be observed by others** during the course of the study, this must be noted as well.

[**If audio or video recordings will be made**, include an explanation regarding who will have access to the recordings, if the recordings will be used for educational purposes, and when the recordings will be destroyed.]

[**If identifiable information from student education records will be disclosed to the study team**, insert the following language:] The study will involve accessing information from your student records which is protected by a law called FERPA. Your education records must be kept secure by your school, and can only be disclosed to researchers with your permission. The records we need to access for this study include the following: [Insert description of student education records to be disclosed to the study team].

**WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?** (insert if applicable)

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify your child will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent

**COMPENSATION**

There is / is not compensation for participating in this study.

If there is compensation, include details and any conditions of payment, including if partial payment is applicable. For example: you will receive $ X for participating in each study component. Describe how voluntary or involuntary withdrawal or termination affects compensation. If compensation for time is provided, then a portion of the compensation must be provided (prorated) even if the person terminates their involvement prior to completing the study. See IRB and OBO policies for reporting compensations when studies involve UNI participants.

**RIGHT TO REFUSE OR WITHDRAW**

Your decision to participate is completely voluntary. You are free to withdraw from participation at any time or to choose not to participate at all, and by doing so, you will not be penalized or lose benefits to which you are otherwise entitled.

[Explain any circumstances where participation may end without regard to the participant’s consent.]

**WHO TO CALL WITH QUESTIONS OR PROBLEMS**

If you have questions regarding participation in this study or about the study in general, please contact insert name / Email/ Phone Number of the research team contact or, (if appropriate) the investigator’s faculty advisor name at the Department of enter at the University of Northern Iowa at email or phone number.

If you have questions about the rights of research participants and the research review process at UNI, you may contact the IRB Administrator at the Office of Research and Sponsored Programs at 319-273-6148 or rsp@uni.edu.

**AGREEMENT**

I am fully aware of the nature and extent of my participation in this project as stated above and the possible risks arising from it. It is my responsibility to notify the researcher if I experience dizziness, nausea, lightheadedness, unusual pain, or any response that I find unusual or unexpected during or after exercise. I hereby agree to participate in this project. I acknowledge that I have received a copy of this consent statement. I am 18 years of age or older.

**Signature of Participant**: Date

**Printed Name of Participant**:

**Signature of Investigator**: Date

**Signature of Instructor/Advisor**: Date

*1.* *Provide a copy of the consent form to the participant and keep one for your records.*

*2.* *Signed forms must be securely maintained for at least* ***5*** *years after the end of study activities.*

*3.* *It is the responsibility of the PI and Advisor (if applicable) to adhere to all data storage requirements.*