

**UNIVERSITY OF NORTHERN IOWA
HUMAN PARTICIPANTS REVIEW
INFORMED CONSENT TEMPLATE**

Template for Writing a Consent Text for Studies Involving Exercise

Use second person language except for agreement statement at the end.
Substitute “your child” for “you” when this is a parental permission form.
Feel free to skip headings and combine paragraphs, when appropriate.

Project Title: (as it appears on the IRB application)

Name of Investigator(s): _____

Invitation to Participate: The researcher must provide a formal invitation to take part in the research project. For example: “*You are invited to participate in a research project conducted through the University of Northern Iowa. The following information is provided to help you make an informed decision about whether or not to participate*”.

Nature and Purpose: State clearly and accurately what the study is designed to discover or establish. Typically one or two concise sentences is sufficient.

Explanation of Procedures: Describe all procedures to be followed, including their purpose(s), duration, frequency, use of any audio or video recording, what will happen to the data/information at the end of the study. Include enough detail that the participant has a reasonable idea of what he/she will be doing and what topics the research will address. 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.*”

Also include information about the training and experience of the researchers. For example: “*The researchers have the training and experience to direct the study’s procedures. Specifically,* (give training, certifications, and/or experience of the person who will be performing the testing or training, including CPR/First Aid).

Privacy and Confidentiality: State the way the participant’s confidentiality will be maintained: persons or organizations to whom information from the study will be furnished, nature of the information furnished, purpose of the disclosure. For example: “*Information obtained during this study which could identify you will be kept confidential. The summarized findings with no identifying information may be published in an academic journal or presented at a scholarly conference*”. If you have dual roles, such as a clinical role (ATC or strength and conditioning) and researcher role, clarify your roles regarding privacy and confidentiality. For example: “*As a certified athletic trainer for the team, I may use your data to personalize your rehabilitation plan. Additionally, I will share your information with (coaches or whoever) in order to (why share data).*”

If data may be saved and used in future research, indicate that. If recordings or transcripts will be used, indicate who may see them, and whether direct quotes may be published. If participants’ performance may be observed by others during the course of the study, this must be noted as well.

If some study procedures will include electronic data collection or storage, add a statement about technology similar to this: “*No guarantees can be made regarding the interception of data transmitted electronically.*”

Discomfort, Risks, and Costs: Describe any physical, psychological, social, legal, and/or economic risk(s) or cost(s) resulting from the project. 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).

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, and a cardiac event. Risks will be minimized by researchers evaluating a implementing a standardized exercise protocol (warm-up and cool down), and having an emergency plan in place to follow if needed.”
2. Body Composition
 - a. 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.”*
 - b. 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.”*
 - c. 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.”*
 - d. 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.”

All studies involving exercise must have a written emergency plan (guidance can be found on the [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.

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.”*

Include information about responsibility of medical care. For example: *“In the unlikely event that any injury or illness occurs as a result of participation in this research, you will be responsible for the cost 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.”*

Benefits and Compensation: Describe any direct benefit(s) that may result from the study. Benefits might include improved physical or mental health (e.g., from treatment), improved skills, etc. Compensation is different than benefit and would include cash, gifts, or academic credit provided for the person’s time or travel expenses. If the individual participant will receive no direct benefit or compensation, this should be stated. If applicable, describe how voluntary or involuntary withdrawal or termination affects benefits. Note that compensation should be equivalent across participant groups and cannot be used to coerce participation. That is, if compensation for time is provided, then a portion of the compensation must be provided (pro-rated) even if the person terminates their involvement prior to

completing the study. For example: “No direct benefits to participants are expected, but this research may generate important information about X. In addition, you will receive \$ X for participating in each study component.” (See information in IRB Policies about compensation reporting if the study involves UNI participants.)

Right to Refuse or Withdraw: Provide information about the voluntary nature of participation and the ability of the participant to stop at any time without penalty. For example: “Your participation 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 from. The researcher also has the right to terminate or restrict your participation at any time. You may request at the time of withdrawal that all of your data be excluded from the research.” Explain any particular circumstances where participation may end without regard to the participant’s consent.

Questions: Participants should be able to seek additional information about the project. For example: “If you have questions about the study or desire information in the future regarding your participation or the study generally, you can contact (investigator) at 319-==== or (if appropriate), or the project investigator’s faculty advisor _____ at the Department of _____, University of Northern Iowa 319-273-====. You can also contact the office of the IRB Administrator, University of Northern Iowa, at 319-273-6148, for answers to questions about the rights of research participants and the study review process.”

Agreement: Include a statement similar to this:

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)

Provide a copy of the consent form to the participant and keep one for your records. Signed consent forms must be maintained for inspection for at least 3 years after the end of study activities.