

INFORMED CONSENT DOCUMENT

Title of Study:

Investigators: *[List all investigators and key personnel, who will be responsible for obtaining informed consent or data collection from participants.]*

This is a research study. Please take your time in deciding if you would like to participate. Please feel free to ask questions at any time.

INTRODUCTION

The purpose of this study is to *[give a general description of the study and the kind of information that it is hoped will be gained. For example, learn more about community attitudes towards a new recreation center; learn if attending preschool gives children an advantage when they start kindergarten, etc.]*. You are being invited to participate in this study because *[describe the reason they are being asked to participate. For example, they are a student, they are a resident of Ames, they have a sports-related injury, etc.]*

Comment [MJM1]: This should be consistent with the aims of the study (on the application)

Comment [MJM2]: This usually refers to the inclusion criteria

DESCRIPTION OF PROCEDURES

If you agree to participate in this study, your participation will last for *[list the expected duration of the subject's participation. For example, two months and will involve three visits to the department; will consist of this appointment and will last for about a half an hour.]* During the study you may expect the following study procedures to be followed: *[List all procedures step-by-step that the subject will experience, for example, you will be asked to complete a survey about your attitudes towards alcohol; you will be asked to walk on a tread mill for 15 minutes and then your heart rate and blood pressure will be checked.]*

Comment [MJM3]: Be honest! Let participants know what they're getting into.

[If audio or visual recordings will be used, include how this will be done and when they will be erased. For survey and questionnaire studies, add the following statement. "You may skip any question that you do not wish to answer or that makes you feel uncomfortable."]

RISKS

While participating in this study you may experience the following risks: *[List all physical, emotional, psychological, legal, pain, inconveniences and privacy issues. If there are no known risks, state that there are no foreseeable risks at this time from participating in this study.]*

Comment [MJM4]: In some sense, it is OK to have risks associated with the study, as long as you attempt to do something to mitigate those risks, e.g., informing participants about the risks, providing a list of services in the community, having a spotter, etc.

BENEFITS

If you decide to participate in this study there *[may be no/will be no – select the appropriate phrase]* direct benefit to you *[A benefit is defined as a "desired outcome or advantage."]* It is hoped that the information gained in this study will benefit society by _____
_____. *[Describe how the information gained in this study will help society, e.g., providing*

valuable information about curriculum development; providing valuable information about a new prosthesis.]

ALTERNATIVES TO PARTICIPATION

[List the alternatives if the study involves treatments or therapy. Omit if the whole section if not applicable.]

COSTS AND COMPENSATION

You *[will/will not]* have any costs from participating in this study *[If there will be costs, state specifically what they will be.]* You *[will/will not]* be compensated for participating in this study. You will need to provide your social security number (SSN) *[the social security number is required for payments of \$75 or more]* and address in order for us to pay you. *[Participants should be informed that the information allows the University to fulfill government reporting requirements and confidentiality measures are in place to keep this information secure. Subjects may be given the opportunity to forego receipt of payment(s) and continue in the research study if they decline to provide their social security number and address.]*

Information regarding documentation required for participant compensation may be obtained from the Controller's Department; 294-2555 or <http://www.controller.iastate.edu>.

If a person is to receive money or another token of appreciation for their participation, explain when it will be given and any conditions of full or partial payment e.g., If you decide to not continue your participation in the study, you will be compensated \$5 for each visit that is completed. It is considered coercive to make completion of the entire study the basis for compensation.]

If extra credit will be given to students for participating please list the alternatives for earning extra credit besides participating in the research e.g., writing a research paper, participating in other research projects.]

PARTICIPANT RIGHTS

Your participation in this study is completely voluntary and you may refuse to participate or leave the study at any time. If you decide to not participate in the study or leave the study early, it will not result in any penalty or loss of benefits to which you are otherwise entitled. *[If applicable, list any foreseeable circumstances and/or reasons that the subject's participation may be terminated.]*

RESEARCH INJURY

Emergency treatment of any injuries that may occur as a direct result of participation in this research is available at the Iowa State University Thomas B. Thielen Student Health Center, and/or referred to Mary Greeley Medical Center or another physician or medical facility at the location of the research activity. Compensation for any injuries will be paid if it is determined

Comment [MJM5]: This is extremely important and is often overlooked!

Comment [MJM6]: This can usually be deleted

under the Iowa Tort Claims Act, Chapter 669 Iowa Code. Claims for compensation should be submitted on approved forms to the State Appeals Board and are available from the Iowa State University Office of Risk Management and Insurance. *[Add this Iowa Tort Claims statement if there is potential for physical risk(s) to the subject. If there are no potential physical risks this section may be deleted.]*

CONFIDENTIALITY

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies *[list all other applicable groups e.g., NIH, the sponsor]*, auditing departments of Iowa State University, and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy your records for quality assurance and data analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken *[e.g., subjects will be assigned a unique code and letter and will be used on forms instead of their name. If identifiers will be kept with the data this must be also stated. Also provide specific details of who will have access to study records and how they will be kept confidential, e.g., locked filing cabinet, password protected computer files. Specify the duration of time the data will be retained before erasure or destruction.]* If the results are published, your identity will remain confidential.

Comment [MJM7]: This is also overlooked or not consistent with application

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study.

- For further information about the study contact *[investigator name and phone number; for a student project list the name of the major professor or supervising faculty member's name and contact information].*
- If you have any questions about the rights of research subjects or research-related injury, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Responsible Research, Iowa State University, Ames, Iowa 50011.

Comment [MJM8]: Be sure your name and contact info is correct/updated, include major prof's info too.

PARTICIPANT SIGNATURE

Your signature indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. You will receive a copy of the written informed consent prior to your participation in the study. *[The regulations require a statement that the informed consent document shall be given to the person signing the form. If this is an online*

survey, please include a statement reminding participants to print a copy of the informed consent for their own files or provide information about where they may obtain a copy.]

Comment [MJM9]: Participants need to receive a full copy of this document

Participant's Name (printed) _____

(Participant's Signature) (Date)

[Include the Parent/Guardian/Legally Authorized Representative signature line only if applicable to your study.]

(Signature of Parent/Guardian or Legally Authorized Representative) (Date)

INVESTIGATOR STATEMENT

I certify that the participant has been given adequate time to read and learn about the study and all of their questions have been answered. It is my opinion that the participant understands the purpose, risks, benefits and the procedures that will be followed in this study and has voluntarily agreed to participate.

(Signature of Person Obtaining Informed Consent) (Date)