INFORMED CONSENT DOCUMENT

Title of Study:

Investigators: List all investigators and key personnel who will be responsible for obtaining informed consent or collecting data 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.] You are being invited to participate in this study because [Describe the reason they are being asked to participate, any inclusion criteria, etc.]. If applicable, add: You should not participate if [Describe any exclusion criteria (e.g., under age 18, have certain health conditions, etc.).].

Procedures

If you agree to participate, you will be asked to [In a step-by-step fashion, describe **ALL** steps and procedures you will follow, including their purposes, how long each step will takes, and any repetitions.].

For surveys, interviews, focus groups, include the types of questions subjects will be asked or the topics to be discussed.

If video or audio tapes will be used to record participation, this must be stated.

Include the number of visits or contacts for research that involves contact at multiple time points.

This study will take approximately [indicate the length of time the subjects will be participants in the study during each interval (xx minutes/hours over xx sessions)].

Note: The procedures and duration can be combined if desired (e.g., you will be asked to complete a survey about your attitudes toward alcohol use that should take about 20 minutes; you will be asked to visit our lab once per week for the next four weeks—each visit should last about one hour; your visit to our facility will take about 45 minutes and you will be asked to complete an exercise history questionnaire and walk on a treadmill for 20 minutes).

Risks

While participating in this study you may experience the following risks: [List any and all physical, emotional, psychological, legal, pain, inconvenience, and privacy issues. If there are no known risks, state that there are no foreseeable risks at this time from participating in this study. Risks must be explained, including the likelihood of the risk]. If you are negatively impacted at any time during or after this study, please contact [Add the contact information of the person, organization, or business participants should contact in addition to phone numbers to "emergency services" for both their physical and mental health.] and Drake IRB at irb@drake.edu or 515-271-3472.

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, advance knowledge, etc.].

Compensation

If you participate, you will receive [Include payment or reimbursement information here. Explain when disbursement will occur and conditions of payments. Delete this section if it is not applicable.].

If course credit or extra credit will be given to students for participating, please specify the amount of credit and 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 the study involves a survey, interview, focus group, or other similar methods, add: You can skip any questions that you do not wish to answer.

If applicable, list any foreseeable circumstances and/or reasons that the subject's participation may be terminated.

Confidentiality

Any information obtained in connection with this research study that can be identified with you will be disclosed only with your permission; your results will be kept confidential. In any written reports or publications, no one will be identified or identifiable and only group data will be presented. However, federal government regulatory agencies [list all other applicable groups (e.g., NIH, the sponsor)], auditing departments of Drake 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. **If the study is regulated by the FDA, a statement that the FDA may inspect or copy records must be included.**

To ensure confidentiality to the extent permitted by law, the following measures will be taken: [e.g., describe the use of any coding systems, whether identifying information will be collected or retained, who will have access to the data, etc. If identifiers will be kept with the data, this must be also stated. Also provide specific details of how data and any identifiers will be kept confidential, (e.g., locked filing cabinet, password protected computer files, access limited to the researchers, etc.). Specify the duration of time the data will be retained before erasure or destruction.].

Contacts and Questions

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) 271-3472, irb@drake.edu.

You may keep a copy of this form for your records

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Statement of Consent:

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 may keep a copy of this form for your records. Even after signing this form, please know that you may withdraw from the study at any time.

I consent to participate in the study. [If you are video- or audio-taping your subjects, include a statement such as "and I agree to be videotaped."]

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)

Witness's Name (printed) _____

_____ _____

(Witness's Signature) (Date)